IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

THE CITY OF HUNTINGTON,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01362
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	
CABELL COUNTY COMMISSION,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01665
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	

BENCH TRIAL - VOLUME 34
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JULY 2, 2021

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PROCEEDINGS had before The Honorable David A. Faber, Senior Status Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on July 2, 2021, at 9:00 a.m., as follows:

THE COURT: All right.

Do you want to call your witness?

MR. SCHMIDT: Yes, Your Honor. We're ready to go, if that works for the Court.

THE COURT: Yes, please.

COURTROOM DEPUTY CLERK: Sir, would you please state your name?

THE WITNESS: Christopher Gilligan.

COURTROOM DEPUTY CLERK: Thank you. Please raise your right hand.

DR. CHRISTOPHER GILLIGAN, DEFENSE WITNESS, SWORN

COURTROOM DEPUTY CLERK: Thank you. Please take a seat.

THE COURT: Good morning, sir.

THE WITNESS: Good morning.

MR. SCHMIDT: Your Honor, it's good to be back. We call Chris Gilligan as our first witness.

May we proceed?

THE COURT: Well, it's good to see you, sir.

MR. SCHMIDT: Thank you.

THE COURT: We missed you.

MR. SCHMIDT: I missed being here. I missed you. May we proceed?

THE COURT: Yes, please.

MR. SCHMIDT: Okay.

DIRECT EXAMINATION

BY MR. SCHMIDT:

Q. Good morning, Dr. Gilligan. Please introduce yourself to the Court, if you would, in terms of name and your position, please.

A. Good morning. I'm Chris Gilligan and I serve as the Chief of the Division of Pain Medicine at Brigham and Women's Hospital in Boston.

Q. What is it that has made you dedicate your career to pain medicine, the discipline that you just mentioned?

A. When you think about what brings a patient to a doctor, one of the main reasons, one of the primary reasons the patients come, is to get relief of -- from pain and, also, for patients who have severe chronic pain conditions, those conditions, not just because of the obvious suffering from pain, but they also prevent patients from -- from functioning, from working; in many cases, taking care of their families, doing the things they need to do and want to do and essentially can take their life away. And so, when we're able to successfully treat those patients, it's

incredibly rewarding.

Q. Prescription opioids over the course of your career, have they been an important part of pain treatment and pain management?

A. Yes, they have.

Q. Who's charged with making the judgment about when and by whom prescription opioids should be used?

A. Principally, that's doctors. It's clinicians who are in the exam room with the patient and are getting the information about the patient's case, are examining the patient, have the training and the education to make that decision and, therefore -- and also have the responsibility and the authority to make that decision.

Q. From your experience, do distributors play a role in deciding whether doctors prescribe opioids or other medicines?

A. No, they do not.

Q. Do they play a role in determining the level of opioids that doctors prescribe?

A. No.

Q. And I'd like to dive into those opinions over the course of our exam but, first, I want to take a step back and spend a little more time giving the Court a sense of your background, if we could. Let me start off by asking where you went to college?

A. I went to Harvard College.

Q. And what did you do after college and before medical school?

A. I went to Cambridge University in England and did an M. Phil, an M. Phil degree, a Masters degree.

Q. Where did you go to medical school after that?

A. I went to Yale Medical School.

Q. What was it that made you decide you wanted to go to medical school?

A. When I was 15, I spent a summer in France and stayed with a family where the father was a doctor and got to know him very well and had tremendous respect for him, and decided that I wanted to be a -- wanted to follow that path.

Q. Okay. And you've done some different things over the course of your career that I want to briefly touch on. Could you first walk us through what you did between graduating from medical school up to the year 2000?

A. Yes. So, I graduated from medical school in 1996. I did a one-year surgical internship at New York Hospital in New York.

After that, I moved up to Boston to Brigham and Women's Hospital to serve as a surgery resident.

Then, I got to the two-year research portion of a seven-year surgery residency and I got permission to go back to school during that two-year research period. So, I went

to Harvard Business School.

After Harvard Business School, I was intending to just go back to my surgery residency, but my professors at the business school said you need to get some -- some business experience. I'd only been a doctor. So, I did Life Science Venture Capital and then I also went and I served in the Army in Israel. I'm -- my family -- my mother is Jewish, I'm Jewish, and I went to Israel, did my military service there.

Q. And how long did you serve in the military in Israel?

A. About a year and a half.

Q. Did that include a combat function?

A. Yes, it did.

Q. And can you tell us just a little bit about that?

A. I was a battalion doctor in the Golani Brigade, which is an infantry brigade. So, we were principally tasked with dealing with a lot of different things.

Q. Okay. Did you do further medical training after completing that service and that work you described in 2004?

A. Yes. After that, I went back to Brigham and Women's and did the combined emergency medicine residency at Brigham and Women's and Mass General Hospital. I shifted from surgery to emergency medicine and completed my emergency medicine residency there and then I stayed on at Mass General to do a pain medicine fellowship.

Q. And what prompted the shift from a surgery focus to a pain medicine focus for you?

A. So, I had been on a cardiac surgery track and I saw that cardiac surgery was really -- patients were being better treated by minimally invasive therapies and interventional cardiologists and such were developing. And I realized that in pain medicine there was an element where we could do the same thing for patients to try to -- to try to develop better, simpler, safer procedures and treatments to help patients get better.

Q. As I understand your CV, since finishing that fellowship in anesthesia and pain medicine, you've been at different teaching hospitals in Boston; is that correct?

A. That is right. After finishing the fellowship, I stayed on staff at Mass General Hospital, which is one of the teaching hospitals for Harvard Medical School.

Then I went to Beth Israel Deaconess Medical Center, which is another of the teaching hospitals for Harvard Medical School.

And then, since 2016, I've been serving as the Chief at Brigham and Women's, which is also one of Harvard's teaching hospitals.

Q. And can you comment just on the standing of Brigham and Women's in the -- in the medical -- in the broader medical community?

A. It's one of the big academic medical centers in Boston charged with taking care of patients, doing research to try to advance our different fields, and teaching medical students, residents, fellows. Hopefully, the next generation of leaders.

Q. In terms of teaching, is it affiliated with any universities?

A. So, it is a teaching hospital for Harvard Medical School.

Q. Are you -- are you board certified in any areas?

A. I'm board certified in emergency medicine and in pain medicine.

Q. Beyond being board certified yourself, do you play any role in the board certification process for other doctors?

A. I do. I write the -- some of the board examination questions for the Pain Medicine Boards.

Q. Having walked through your background --

MR. SCHMIDT: May I approach the witness, Your Honor?

THE COURT: Yes, please.

BY MR. SCHMIDT:

Q. I'd like to just dive into a little bit of -- a little bit more detail into some of the areas of your background.

MR. SCHMIDT: Am I going to break anyone's heart if I erase this?

THE COURT: You're a day late on the birthday cake.

MR. SCHMIDT: That's really sweet.

BY MR. SCHMIDT:

Q. Throughout your career, have you been involved in patient care, teaching and research?

A. Yes. That would be a good description of -- we talk about a three-part mission, which is our mission, and that's a good description of how I've spent my time.

Q. Okay. I'm going to just walk through some of those, starting with patient care. Can you give us a sense of the range of pain conditions that, in your work, you treat?

A. So, we treat really a broad and I think a complete range. We treat patients with back and neck pain, hip and knee pain from arthritis. We treat a lot of patients. We're the hospital associated with the Dana-Farber Cancer Institute. We treat conditions that are just defined by the pain, things like shingles. We treat a lot of patients with headaches.

And then, a wide range. Patients, for example, may have an autoimmune condition like rheumatoid arthritis, things like that, that cause pain, and we treat -- we treat that, as well.

Q. Is that true or not true in terms of the patient population that you see? Is it a narrow range, a focused

range, or a broad range?

A. So, we're a teaching hospital and we see the entire range. We see -- we see patients who are homeless. We see patients who are royalty and fly in from other countries.

Q. Do you have just -- not to the person, but a rough estimate of what order of magnitude of patients you've seen and cared for over the course of your career?

A. So, I see patients two and a half days a week. A typical clinic day for me is about 25 patients give or take. My whole career in pain medicine, I've seen -- at least that many days a week I've spent time seeing patients. Other times, it's been more than that. So -- and I finished fellowship in 2008.

Q. So, are we talking hundreds more, thousands?

A. I think -- I think it's thousands.

Q. Okay. And could you orient us to how that tracks in the real world just to illustrate when was the last time you saw a patient?

A. Yesterday afternoon right before I went to the airport.

Q. Okay. When is the next time you will see a patient?

A. I'm taking vacation next week.

Q. Okay.

A. So, the following Monday morning.

Q. Got it.

Do you -- in addition to seeing patients yourself, do

you also supervise other physicians who are responsible for providing pain management medical care to patients?

A. Yes. So, we have a pain medicine fellowship and every year we train ten fellows in pain medicine. In addition, we have the residents from Brigham and we also have a lot of residents who come through and medical students who come through.

Q. Could you give us a sense of what that entails when it comes to the people you're overseeing, their medical treatment and, specifically, their use of prescription medicines?

A. So, we see patients typically together with the trainees, the fellows, or the residents, to evaluate the patient together, make a plan together, and then they -- they also participate with us in writing prescriptions, doing procedures, et cetera.

Q. Are there any other leadership roles that you play at Brigham and Women's?

A. Yes. So, I'm -- I'm one of the Vice Chairs of Anesthesia. I'm also the Director of the Spine Center at Brigham and Women's Hospital. And then I serve on the Executive Committee of the Brigham Comprehensive Opioid Response and Education Committee, which is a committee at the Brigham responsible for, as the name implies, both overseeing opioid prescribing and educating physicians and

other clinicians about opioid prescribing.

Q. Is that a steering committee?

A. That's a steering committee, yes.

Q. Okay. And could -- does serving on that steering committee include any role in creating guidelines for doctors?

A. Yes. We write the guidelines for clinicians at Brigham and Women's about appropriate prescribing of opioids and other -- and other related topics.

Q. Just at a high level, what is the purpose of guidelines like that?

A. I would say the purpose is to try to give clinicians guidance on essentially how to get it right. What is the right balance? Everything in medicine is a balance of risk and benefit and on a specific topic like that you're trying to give guidance about how to best and most appropriately get that decision right. Those are decisions that, typically, the correct answer is not going to always be yes. The correct answer won't always be no. And you're trying to give people guidance about where the balance should lie.

Q. Let me shift gears and ask you about your teaching work. Are you affiliated or are you on the faculty at any medical school?

A. I'm on the faculty at Harvard Medical School.

Q. What do you teach there?

A. Really, the folks who I've mentioned, the fellows, residents, medical students, where we teach them about the field of pain medicine, how to practice it, how to evaluate patients and the research, et cetera.

Q. And how long have you been doing that?

A. Since 2008.

Q. Over a decade? Lastly, your research, do you conduct pain research?

A. Yes, I do. Principally clinical trials.

Q. And can you give us a sense of what that pain research involves?

A. So, it's really a question of trying to take potential new and perhaps better therapies and evaluate. Do they work? Are they safe? Who do they work for? Who do they not work for? What could be their role? Could they represent a better way to treat at least a certain group of patients that -- that we try to treat?

Q. Does that include doing research of clinical trials?

A. Very much so. Clinical trials is the focus of it.

Q. Are some of the treatments that you're looking at in your clinical trial research potential alternatives to prescription opioid treatments for pain?

A. Yes, they are because if we have other alternative therapies that work well and are safe for certain patients and can get them pain relief, return their function, et

cetera. Then, for at least a certain number of those patients, you wouldn't need to be treating them with opioids.

Q. Have you published studies and articles in peer-review journals?

A. Yes, I have.

Q. And by my count you've got about a dozen; does that seem right?

A. That might be about right.

Q. And I think I undersold you. I think it's about two dozen, looking at my notes.

A. That seems more right.

Q. Okay. I've had trouble with my dozen counting in this -- in this court. So, it pays to check my math, especially for me.

Do you also serve as a peer reviewer for scientific journals?

A. Yes, I do.

Q. Has that included leading medical journals?

A. Yes, it has.

Q. Can you give us a couple examples of that?

A. The Lancet, The New England Journal of Medicine, some of the more well-regarded journals in the field, specifically, of pain medicine.

Q. And that was going to be the next question I asked you.

Has that included specifically pain management journals in addition to general journals like Lancet and like The New England Journal of Medicine?

A. It has, yes.

Q. Have you also served in an editorial role in journals?

A. Yes. I serve on the Editorial Board of one of the pain medicine journals and, in September, I'll become an Editor in Chief of a different one.

Q. And last question in this area. Have you undertaken service for the Department of Defense related to pain treatments?

A. Yes. I evaluate grant applications with the Department of Defense on topics in the field of pain medicine where they're deciding which ones to fund, as they're trying to do similar things to what we talked about, evaluate, find new and better treatments for pain conditions.

Q. I'm going to put you on the spot a little bit, Dr. Gilligan, and ask you a couple of questions on some of the recognitions you've received, not wanting to make you feel uncomfortable in doing so.

Over the course of your career have you received awards for some of the work that you've done?

A. Yes, I have.

Q. And I want to just ask you basic questions about a few of those. One was you have listed on your CV that you were

part of a summit on opioid abuse at the White House in 2014. Can you give us a sense of what that involved?

A. So, it was -- as the name implies, it was a summit at the White House looking at the topic of opioid abuse. I think my role was to be there as a specialist in pain medicine because to address that topic you both have to look at the area of addiction medicine, but also, you have to look at the topic of pain medicine because how are you going to treat pain.

Q. You also have listed some citizenship awards and something called a Fellowship Excellence Award. Can you tell us what those are?

A. Those are recognitions from the hospitals, the Department of Anesthesia, for -- I think for contributing to the mission of the department and for -- for running a fellowship in pain medicine that was well regarded.

Q. Okay. And this is the hardest one for me personally to ask you about. It looks like you've gotten something from the Boston Red Sox. Can you tell us about that?

A. They also give -- give an award, I think, for physicians who they think have worked hard to treat their patients and work in our community.

Q. Let me shift gears a little bit. Have you served as an expert witness before this case?

A. Yes, I have.

Q. How much of your time does that kind of work make up?
A. That's typically a very small part of what I do.
Q. Have you served as an expert witness for the government in prior matters?
A. Yes, I have.
Q. And without diving into details, can you give us just a general sense of what that entails?
A. So, I served as an expert witness for the U. S. Attorney's Office. I think that's Department of Justice and the FBI for a doctor who was accused in a criminal case of -- I think the accusation was stopping being a doctor and being essentially a drug dealer.
Q. And I saw one time where you were asked to testify by the government in a case involving an opioid company, but you weren't allowed to do so. Can you tell us what happened there?
A. Yeah. So, some executives at Insys Pharmaceuticals were charged with criminal charges that were related to -- Insys produced opioids or does produce opioids. The defense attorneys for them came, met with me a few times, asking me to serve as a witness for the defense, an expert witness.

Then I went to my department. We have to get permission from our department to serve as an expert witness. The leadership in my department said that I should not serve as an expert witness and I told them that.

Subsequently, the government --

Q. I'm sorry. Did you agree with that view?

A. Actually, I did, yes.

Q. Okay.

A. Subsequently, the attorneys from the government, from the U. S. Attorney's Office, asked if I would serve as their witness, their expert witness in that same case. I told them that I was surprised because I told them about the conversations I had had with Insys. They said they didn't think it was problematic, but the judge said that I should not serve as an expert witness since I had both talked to the defense and then subsequently to the U. S. Attorney's Office.

Q. Okay. You're being compensated for your work in this case. Can you share with us your hourly rate?

A. My rate is $800.00 per hour.

Q. And in terms of different prescription opioid cases where we have worked with you on behalf of McKesson, how far back in time does that reach?

A. For the different cases, I think it's about two years.

Q. Has your work included going back through the literature developments in the medical field and reviewing that kind of material?

A. Yes, it has.

Q. Has your work included making an effort to fully review

all of McKesson's documents, or ABDC's documents, or Cardinal's documents?

A. No. I haven't done an in-depth review of all of their documents, no.

Q. And why is that?

A. I'm a doctor. I'm an expert in pain medicine. I'm, frankly, not an expert in healthcare distributors and their business.

Q. Got it.

I want to just wrap up on some of these points. Throughout the course of your career, has your work and your training focused on the medical management of pain?

A. Yes, very much so.

Q. Have you been directly involved with the use of prescription opioids and discussions about the standard of care for using prescription opioids since you were in medical school back in the 90s?

A. Yes, I have.

Q. And as part of your professional work and as a part of your work in this case have you had occasion to study prescribing patterns from before you were in medical school in terms of what's reflected in literature and things like that?

A. Yes, I have.

Q. From doing that work, have you reached opinions on pain

management and the use of prescription opioids in pain management for purposes of this lawsuit?

A. Yes, I have.

Q. Are you offering all of the opinions you offer in those areas to a reasonable degree of medical certainty?

A. I am.

MR. SCHMIDT: Your Honor, at this point, we move to admit Dr. Chris Gilligan as expert in pain management and the risks and benefits of prescription opioids.

THE COURT: Any objection? Hearing none, the Court --

MR. FARRELL: Judge, yes. If you don't mind, may I voir dire the witness?

THE COURT: Yes.

CROSS EXAMINATION

BY MR. FARRELL:

Q. Good morning, Dr. Gilligan.

A. Good morning.

Q. A couple of questions.

Are you licensed in West Virginia?

A. No, I am not.

Q. Have you ever practiced medicine in West Virginia?

A. No.

Q. Have you provided healthcare for West Virginians, to your knowledge?

A. Not -- not that comes to mind immediately, no.

Q. And then, real quick, you mentioned the Chair of Pain Medicine. In part of your administrative role or your oversight of physicians, do you monitor the prescribing practices of those doctors?

A. Yes, I do.

MR. FARRELL: No objection and no further questions.

THE COURT: The Court finds that Dr. Gilligan is an expert in the field of pain management and the risks and benefits of prescription opioids.

Just curious, what was your Cambridge college?

THE WITNESS: Jesus.

THE COURT: Okay.

BY MR. SCHMIDT:

Q. So, Dr. Gilligan, I'd like to ask you about the condition of pain and then ask you about prescription opioids as a treatment for pain. Let's start with the pain first. Could you tell us just at a high level from your experience how pain impacts the patients you see and why it's important to treat pain?

A. So, we see patients who their pain is at the level that they're coming to go see a pain specialist. And many of our patients have chronic pain conditions. And for a lot of those patients it's -- their pain is severe, so just their

level of suffering is severe.

But also very, very important is that, in many cases, they can't work or they can't work the way they want to. As I mentioned before, they can't take care of their family the way they want to. They can't participate in the community, socialize, exercise, et cetera. And so, not only do they have the suffering from the pain, but they have essentially -- we talk about their life being taken away from them by the pain and by the limitation in function from the pain.

So, frankly, some of these cases are -- if you're sitting in the room with a patient are very, very brutal.

Q. Have you seen over the course of your career the impact that pain directly has upon patients who suffer from it, particularly chronic pain?

A. Yes. I would say on a daily basis when we're -- where we're in clinic I see that.

Q. Are you familiar with published data on trying to quantify the costs and the number of people affected by pain, including chronic pain?

A. Yes, I am.

Q. I'd like to ask you about some of that data, if I may. I'm going to show you a document that the Court has seen before, but is not in evidence, MCWV-1170.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

MR. SCHMIDT: And I apologize. I feel like I came back and the big documents came back.

THE COURT: We cleaned out the documents while you were gone, Mr. Schmidt.

MR. SCHMIDT: I know. I'm sorry.

BY MR. SCHMIDT:

Q. And so we know what we're looking at, Dr. Gilligan, if we go to the second page of this document, it's titled -- and we can actually put it up on the screen.

MR. SCHMIDT: Can you switch that?

BY MR. SCHMIDT:

Q. It's entitled Relieving Pain in America. And then, about halfway down, it says it's from the Institute of Medicine. And if we go to the next page, the third page of the document using the numbers in the lower left corner, we can see near the bottom that it's from 2011. Are you familiar with this document from the Institute of Medicine and this report, Relieving Pain in America, from 2011?

A. Yes, I am.

Q. What is the Institute of Medicine?

A. So, the Institute of Medicine is a, frankly, very well regarded group of physicians who have been recognized as leaders and then they will be tasked by the government with writing reports on certain topics that are important to the health of Americans.

MR. SCHMIDT: On that basis, I'm going to move this into evidence as a public report, but if there's an objection, I can lay a little more foundation.

THE COURT: Is there any objection?

MR. FARRELL: No, Your Honor.

THE COURT: It's admitted.

MR. SCHMIDT: Okay. Thank you for that.

BY MR. SCHMIDT:

Q. Just in terms of this specific report, do you have an understanding of how this report came to be?

A. Well, I think it was the government recognizing that this is a topic that was very important to the health of Americans and a need for data on the scope of the problem, the state of treatments, et cetera, what were the unmet needs in the areas that needed more research and they brought together a group of experts in the field, as well as patient representatives or others.

Q. All right. Let's look at Page 38 of this report, if we could. And, again, I'm going to be using the numbers in the bottom left corner, which differ from the numbers in the actual document. And we have it up on the screen. I'm going to read to you the last paragraph that carries over onto Page 39 and ask you to comment on it.

It says pain is a universal experience but unique to each individual. Is that something you see in your medical

practice?

A. Yes, it is.

Q. It then says across the lifespan, pain - acute and chronic - and let me just pause right there. We're well into this trial. I don't know if we've ever defined for the Court what acute and chronic is from a pain management doctor. Can you tell us what the difference between acute and chronic pain is?

A. Sure. So, a couple of things. One is the time frame. We typically talk about pain that's acute lasting 6 or 12 weeks; if pain is chronic, being longer than that, certainly longer than 12 weeks.

There's also a distinction because acute pain is most commonly associated something such as an injury. Someone breaks their arm, there's actually a helpful signal in that. If I -- if I break my arm and it hurts, it's telling me not to move it, and there's some value in that.

Chronic pain is, almost by definition, more than 12 weeks and often is not, at that point, serving a useful function. So, if I break my arm and twelve weeks later it's been set, but it's still hurting severely, that's actually not giving useful information, but there's suffering and there's loss of function.

Q. So, to go back to the start of the sentence, it says across the lifespan pain, acute and chronic, is one of the

most frequent reasons for physician visits, among the most common reasons for taking medications, and a major cause of work disability.

Have you seen all three of those things in your practice in terms of pain as one of the most frequent reasons people see doctors, one of the most frequent reasons they take medicine, and one of the major causes of not being able to work?

A. Yes. I have seen all three of those.

Q. All right. Let's jump ahead, if we could, to Page 47, please. And there's a box there if we make it a little larger that says pain by the numbers. And I want to just walk through a couple pieces of data reported in this report. The first piece of data reported says 100 million, approximate number of U. S. adults with common chronic pain conditions. Do you see that?

A. I do.

Q. Have you seen similar estimates of the number of Americans who have chronic pain conditions?

A. Yes, I have.

Q. And I just want to differentiate between types of chronic pain conditions. Is cancer pain a chronic pain condition?

A. Cancer pain can also be a chronic pain condition. We talk about chronic pain related to cancer and then chronic

non-cancer pain is one of the ways that we divide things.

Q. In terms of chronic cancer pain, can you characterize that at all for the Court? Describe that pain.

A. So, chronic cancer pain, we do think of as a distinct topic. In many instances, somebody may have advanced cancer and they're going to have -- many of those patients will have severe pain, but they also may have -- they, unfortunately, have a limited life expectancy, frankly. For those patients opioids are typically going to be really one of the foundations of how we're going to treat the pain. For most of those patients, opioids will play a central role in how we're going to treat that pain.

Q. And you mentioned non-cancer chronic pain. Could you tell us some of the conditions that cause non-cancer chronic pain and characterize the relative severity of those?

A. So, for non-cancer chronic pain things like severe low-back pain or neck pain, severe hip or knee pain associated with arthritis and, actually, a whole host of things. Some of the autoimmune conditions, rheumatoid arthritis, Crohn's disease, et cetera. Chronic migraines. And the list would go on.

Q. Okay. Just rounding out the questions that I was asking you about this number, this is 2011, 100 million. From your experience, has this number of adults in the U. S. with common chronic pain conditions increased over time or

decreased over time?

A. I think that it's increased over time due to a few things. One, the population has grown. It's gotten so much older. Our population has gotten somewhat heavier and weight is associated with knee and hip arthritis, et cetera. So, I think that, overall, it has grown somewhat.

Q. Let's go to the next line and this is actually the statistic we heard about with another expert, 560 to 635 billion conservative estimate of the annual cost of chronic pain in America. Are you familiar -- have you seen estimates like that in the literature in terms of trying to estimate the economic consequences of chronic pain just on a yearly basis?

A. Yes, I have.

Q. And are they consistent with this number which is north of a half trillion?

A. Yes.

Q. If we then look at the -- let's skip the next bullet which talks about state and federal government expenditures. There's a number of percentages that run down here talking about different pain conditions. Could you just walk through the numbers there that you think are meaningful for us to hear about?

A. Sure. So, I would look at the fourth bullet point for women after having a baby and look for -- at that

percentage. 10 percent have persistent pain at one year. I think that's significant.

I think, for the next bullet point, the patients who have undergone surgery, specifically, the third dash there, that 2 to 10 percent of these patients have chronic postoperative pain that's severe. And what's important there is that it's chronic. That's not right after surgery. That's after they would have been expected to heal up, so to speak.

I think the bullet point just below that, 5 percent of the portion of American women 18 to 65 who have headache 15 or more days per month, I think that's quite significant.

And I think the second to last bullet point, the percentage per U. S. nursing home residents, I would look at the second dash there, that 17 percent have substantial daily pain.

Q. A few more questions about this document.

MR. SCHMIDT: Could we go up to Page 162, please?

BY MR. SCHMIDT:

Q. And if we look here, there's a paragraph -- there's a sub-header that says Patient Access to Opioids. Do you see that?

A. I do.

Q. And it states in this 2011 Institute of Medicine publication a reasonable degree of access to pain medication

- such as the stepped approach of the World Health Organization's pain relief ladder for cancer - has been considered a human right under international law since the 1961 adoption of the U. N. Single Convention on Narcotic Drugs. Do you see that?

A. I do.

Q. And is that -- is that consistent with your perspective in terms of how the medical field views having prescription opioids for appropriate cases?

A. It -- yes, it is.

Q. And then, if we go to the next paragraph, please, it says in the United States, many pain experts agree that physicians should prescribe opioids when necessary regardless of outside pressure as an exercise of their moral and ethical obligations to treat pain. Do you see that?

A. I do.

Q. Is that something you see within the course of your career, that view among many physicians, that you should prescribe prescription opioids where appropriate when necessary as part of a moral and ethical obligation to their patients?

A. Yes, it is.

Q. All right. Let's shift gears a little bit. I want to now talk about treatments for pain and I'm going to touch on prescription opioids in a minute, but before I do, I want to

talk about nonprescription opioid treatments for pain. Are there treatments for pain that don't involve any kind of medicine?

A. Yes, there are. Examples would be physical therapy. Not involving medicine would include different interventions, things like acupuncture, chiropractic manipulation. There's some psychological treatments, things such as teaching patients relaxation techniques, biofeedback et cetera. So, short answer, there are.

Q. Do those types of treatments have limitations in terms of addressing pain?

A. They do. There are some patients who are very much benefited by them and, frankly, with those patients one would likely be stopping there. And then there are other patients who you try each and every one of those that seems appropriate for their case and, unfortunately, it doesn't work. It doesn't give them relief. It doesn't return their function.

Q. When it comes to prescription medicines or just medicines generally, before I turn to opioids, are there other kinds of medicines that can be used to treat pain other than prescription opioids?

A. Yes, there are. We use common anti-inflammatory medications, Advil, Motrin, Aleve, things in that class. So, nonsteroidal anti-inflammatories. We use muscle

relaxants.

There are groups of medications that are not opioids that we use specifically to treat nerve pain. Those are medications such as Neurontin. So, by trade name, Neurontin, and Lyrica, and Cymbalta.

And then there's a whole host that are topical things we have patients put on -- on the -- the Lidocaine patch, for example.

Q. Are there limitations to those kinds of treatments?

A. Yes. Similar to what we just talked about, there are some patients who get excellent relief from them and, perhaps in many of those cases, one would stop there again.

There are other patients who don't get relief or can't tolerate side effects. And then there are some patients where there's a risk so you can't use those medications, where it would be too dangerous to use those medications given that person's specific medical history, accompanying conditions, other medications they take.

Q. And I want to just pick up on an idea you alluded to. You mentioned risks for some patients for those medications' side effects. Do those medications carry their own distinct risks that you have to take into account when deciding whether to use them?

A. Yes. Those medications have their own risks that you have to take into account and, frankly, essentially every

medication that a doctor prescribes has risks and benefits and the job is to look at the individual patient in front of you, take into account all of the information you have available, weigh the risks and benefits of essentially any medication that you're going to prescribe for that patient.

Q. Okay. So, I want to -- I want to turn from those nonprescription opioid treatments to prescription opioids and pick up on that concept that you were just talking about in terms of benefits and risks and weighing those. In your opinion, are there patients for whom the benefits of prescription opioids outweigh the risks?

A. Yes, there are.

Q. And can you talk about why that is?

A. So, when we're weighing the risks and benefits of opioid medications, a few things. One, we can get some information about how high risk a given patient is for developing addiction. If someone is at high risk for developing addiction, they have a history of substance abuse, they have a history of major untreated psychiatric conditions such as bipolar, strong family history of substance abuse, et cetera, would be at higher risk of addiction.

There are other folks who we can identify as being very low risk and there are other factors that come into it, which is what's the patient's condition, the severity of it,

to what extent can non-opioid treatments get that patient pain relief and return to function, and then to what extent are those safe for that given patient. So, there's a whole host of things that come into that risk benefit.

Q. That view you just expressed to us about the benefits outweighing the risks for certain patients, do you understand that to be the consensus of the medical community when it comes to prescription opioids?

A. Yes, I do.

Q. Do you have an understanding as to whether that consensus is reflected in the fact of FDA approval of prescription medicines?

A. Yes. I think that the FDA approval of those medications reflects a consensus that for certain patients, for selected patients' judicious use, the benefits outweigh the risks.

Q. I would like to talk a little bit more about, first, the risks of prescription opioids and then some of the benefits. And to do that I want to use as an illustration point something referred to as a label for a prescription medicine or the prescribing information. Are you familiar with that document for different prescription medicines, the label, or the prescribing information?

A. Yes, I am. We also call it the package insert sometimes.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. Doctor, I've handed you what we've marked as MCWV-1197, which is a label for prescription medicine, and I will apologize to all concerned in advance. We seem to have found the smallest print copy possible of this document. Fortunately, Mr. Reynolds can blow it up on the screen for us.

If we could start in the upper left corner just to make it large, it says Percocet (oxycodone and acetaminophen tablets) C-II, controlled substance II, Schedule II, prescription only. Do you see that?

A. I do.

Q. Are you familiar with -- from your work with this label for Percocet, a prescription opioid?

A. Yes, I am.

Q. And just before we look a little bit at the contents of this, what do you understand to be the purpose of a document like this, the label, and who do you understand it to be written for?

A. So, my understanding is that the purpose of the label is in part for clinicians to tell them what's the indication, which of the medications be -- what is it indicated for, what's -- what are some of the risks of the

medication, something about the pharmacology, the contents of the medication.

Specific things. You know, what you should do if the patient has, for example, reduced kidney function with that medication or interactions with other medications.

And then there's also some information that's directed to patients and to their families in this.

Q. This version of the label has -- it says right below the title we were looking at, it says revised July, 2018. Do you see that?

A. I do.

Q. Do you have an understanding as to whether the label for a given medicine is regularly and periodically updated over time as new information becomes available?

A. My understanding is that they are, yes.

Q. And I want to pick up on something you were telling us about in terms of some of the information. If we look at this label, we see here there's a black box warning. And then, if we scroll down below that past the black box warning, please, it looks like there are different sections, including some of the ones you mentioned.

We see something called the description of the medication. Then, if we go to the next column, we see pharmacokinetics, metabolism and elimination, something you mentioned, indications and usage, contraindications,

warnings, et cetera.

And before diving into just a few of those sections, do you have an understanding that what we're seeing here is written according to a specified format in terms of these different sections and what's supposed to appear, the types of information that are supposed to appear in those different sections?

MR. FARRELL: Objection, Your Honor. I'm not quite sure that the doctor has been identified as an expert in labeling.

MR. SCHMIDT: I think it's something he deals with every day. If it's necessary, I can lay more of a foundation but --

THE COURT: It seems to me that the labeling is well within his field of expertise that I qualified him in. So, I'm going to overrule the objection.

MR. FARRELL: Just to preserve for the record, I don't have any problem with him testifying what's in the label. What I have an objection to is I believe the question of -- is what is his understanding of what the FDA requires to be in the label.

BY MR. SCHMIDT:

Q. So --

THE COURT: I'm going to allow it. Overruled.

BY MR. SCHMIDT:

Q. Dr. Gilligan, from -- I'm not going to ask you -- we haven't asked you to come here as an FDA expert, have we?

A. You have not, no.

Q. I'm going to ask you just some questions about this label from your perspective as a physician. As a physician, do you have occasion to consult with labels for a range of different medicines and gather information from them?

A. Yes, I do.

Q. Does that require you to have basic information about how they're formatted, at a high level, what goes into them?

A. Yes, it does.

Q. And so, when you look at different labels, do you see that they have a specified format across different medications with some of these sections we've been talking about, warnings, indications, contraindications, and specified information in those sections?

A. Yes. This is the typical type content and layout.

Q. And you heard reference to the FDA. Do you know whether these labels are FDA approved?

A. Yes, they are.

Q. Is that relevant to you in your medical practice?

A. It's relevant to us because the information is useful when you're prescribing these, you know, for all of the type of topics that we've talked about. It informs your decision to prescribe or not, and how to prescribe, what dose to

prescribe, et cetera, and it's -- it is important to us that this language has been approved by FDA in terms of feeling comfortable relying on it.

Q. Do you have the understanding that the companies that manufacture these medicines are responsible for the contents of these labels?

A. Yes. My understanding is that -- and my experience, actually, is that there's a discussion between the company and the FDA about what will be -- what will be agreed to go into the label.

Q. And from your experience when this label sets forth the -- well, let me just ask you a question. Without getting into the substance here, what do you understand the indications to tell you as a doctor?

A. So, it tells you what condition FDA has approved the medication for use for.

Q. And then, obviously, what do you understand the warnings to tell you?

A. That they want to make it quite clear to you what the potential risks of the medication in question is, what the medication -- what the specific identified risks of whichever medication it may be are so that you know them and can put them into that risk benefit balance that we talked about.

Q. In terms of determining the substance of what this

label says, including who the medication might be appropriate for, what the warnings that doctors need to understand are, from your experience, do you know of any role that wholesale distributors play in this content?

A. No. My understanding is they play no role in that.

Q. All right. So, let's look at the specific language. And if we could go back to the first page to the black box warning just to try to facilitate the structure here. It says WARNING:, colon, in all caps, and then it lists a series of conditions, addiction, abuse, and misuse.

And then it talks about a risk evaluation, mitigation and strategy. And it looks like those conditions then repeat with a little bit more information further down. Do you see that?

A. I do.

Q. And so, I want to start with the warning about addiction, abuse and misuse. Could you tell us what those terms mean?

A. So, addiction is when a patient develops a compulsive self-destructive craving to use -- essentially an out of control use of -- of a substance and, in this case, oxycodone. There are many substances, of course, that people can get addicted to. So, it's a compulsive, and out of control, and self-destructive use of a substance is addiction.

THE COURT: Just a minute.

Mr. Ackerman?

MR. ACKERMAN: Your Honor, if I may, this document is not in evidence, I don't believe, unless I missed something. And so, I have an objection to displaying it on the board.

MR. SCHMIDT: We'll move it into evidence, Your Honor.

THE COURT: Any objection to it being admitted, Mr. Ackerman?

MR. ACKERMAN: Hearsay.

MR. SCHMIDT: I think, at a minimum, it can come in for the limited purpose of effect on doctors. It's MCWV-1157.

THE COURT: I'll admit it for the limited purpose.

This is helpful to the Court and I -- I think that the limit -- it's permissible for the limited purpose.

Go ahead, Mr. Schmidt.

BY MR. SCHMIDT:

Q. I think you had told us what addiction is. Can you tell us what abuse and misuse are?

A. Sure. So, abuse and misuse, on the other hand, are just taking the medication, we'd say, for a non-medical use; in other words, taking the medication for the sake of euphoria or whatever, whatever it may be, but not taking it

for a medical use to get -- to get pain relief. But someone who is abusing or misusing a drug might be addicted, but they also might not be addicted. They might just be abusing and misusing it without having -- without -- being addicted.

Q. Under that heading it says Percocet exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Can you tell us just at a high level what that's communicating to doctors?

A. So, it's being very -- very clear to the doctors that whether a patient develop -- if patients develop an addiction or if they abuse or misuse the medication that these medications can cause an overdose and that an overdose can be deadly. And so, they are making that very starkly clear.

Q. It continues to say assess each patient's risk prior to prescribing Percocet and monitor all patients regularly for the development of these behaviors and conditions. (See warnings). Do you see that?

A. I do.

Q. Can you tell us what that's counseling doctors to do?

A. So, that's counseling doctors to do some of the things that we talked about before of -- we call it opioid risk stratification, of looking at all of the information that you have about the patient in front of you; in many cases,

using their validated questionnaires that can help you to do risk stratification so to make sure best informed determination, is this patient high risk, medium risk or low risk for addiction abuse and misuse if the doctor prescribes opioid pain medications.

Q. And this reference here to see warnings, let's go back, if we could, to the second column to that section we saw briefly that says warnings. Is this a reference to further information about addiction abuse and misuse?

A. Yes. It's expanding on that topic essentially.

Q. I want to go back to the black box warning, if we could, and look at one more section. If we scroll down a little bit there's also a heading on Neonatal Opioid Withdrawal Syndrome. And then it has warnings about that again with a cross-reference to the warnings section for further information. Do you see that?

A. I do.

Q. We've heard in court about a condition called NAS. Is that related to this condition?

A. Yes. It's essentially another way of saying -- saying that same thing essentially.

Q. And if we go back up to the abuse, addiction and misuse -- addiction abuse and misuse section, just to reemphasize the point, in your experience, do these types of warnings change over time and often become more developed over time?

A. Yes. In my experience, they do change over time and they do have a tendency to become more developed, yes.

Q. In terms of these warnings we're focusing on now, addiction, abuse and misuse, have you always understood those to be a serious risk of opioid abuse throughout your career and your medical training?

A. Yes, I have.

Q. And do you understand that to be a broad understanding within the medical field?

A. Yes, I do understand it to be a broad understanding throughout the field of medicine.

Q. Does that knowledge of the risk of addiction, abuse, misuse impact how you prescribe opioids?

A. Yes, very much so, because it's -- again, with opioid prescribing or all medications it boils down to largely risk versus benefit and, as a key risk, that's a very significant factor in your decision to prescribe or not and, if you do prescribe, what to prescribe, how much to prescribe, how long to prescribe, et cetera.

Q. Can addiction be an extremely serious condition?

A. Addiction can be a fatal condition.

Q. Does the risk in your experience and from your understanding of the science vary across patients you might see?

A. I'm sorry. Can you repeat the question, please?

Q. Yes. I'm sorry. Does the risk from your experience vary across the range of patients you see, the risk of addiction and abuse and misuse?

A. Yes. The risk of addiction, abuse and misuse varies quite significantly across patients.

Q. And can you give us a little more information as to how that's so?

A. Sure. So, we talked already about that there are validated risk stratification questionnaires that you can use with patients. There are also characteristics. And those are some of the things we talked about of a personal history of substance abuse, a family history of substance abuse, a major psychiatric condition, such as Bipolar Disorder, ADHD.

There are also some just demographic factors, age, gender can play into it, so that you can -- you can say not with perfect accuracy, but with very meaningful information one patient is very at high risk. One patient is medium risk. And one patient is low risk. And you can even identify somebody who might be very, very low risk.

Q. And in your experience in your career, you've kind of touched on steps you take with your patients to try to weigh that risk and benefit on an individual patient basis. Taking those steps, can you comment on how common -- how common that you've seen addiction in the patients you treat

with prescription opioids?

A. So, for the patients who I have initiated the opioids, I have not seen a patient who has developed addiction. I have treated patients who were referred to me by other physicians who were on opioids who have developed addiction and misuse and abuse.

MR. SCHMIDT: And I apologize. May I approach, Your Honor?

THE COURT: Yes.

MR. SCHMIDT: I've been sitting up here drinking. I don't know if this is your water. Oh, it is? Okay. I'll give you one more just in case.

THE WITNESS: Thank you.

BY MR. SCHMIDT:

Q. Just to go back to that last answer you gave me about how rare it is in your practice, how do you know that's true in terms of how do you know you're not seeing addiction that you just don't hear about?

A. So, that certainly could be possible, but we're the largest healthcare system in Massachusetts and we have one single computerized medical record where we can see all of the tests, all of the notes, et cetera.

And so -- and if a patient does develop a problem with addiction, it's highly, highly likely that over time they will have an encounter with the healthcare system related to

that. And since we're the biggest healthcare system in Massachusetts and have a single computer record that we see and that we monitor our patients, we see them monthly if they're on opioids, we follow urine toxicology, et cetera. We monitor them closely.

I think it would be extremely unlikely that one of my patients would develop addiction and that I would not be aware of it.

Q. I want to just finish up with some questions about this prescribing information, this label, and then dive into one specific aspect of abuse and misuse with you. I've been referring to this as a black box warning. Do you know what that is from your medical practice?

A. Yes. From a doctor's point of view a black box warning is -- not all medications have a black box warning and the FDA puts on the label of certain medications a black box warning when they feel there's a specific serious risk that they want doctors to be particularly aware of, so they put a black box around it.

We know to look for that, to take it seriously, and they typically put it, in my experience, at the front of the label, again, to emphasize it to clinicians.

Q. One more question on this label. If we go to the second to last column, or third to last column, I apologize, it says medication guide. Percocet. And then it's got an

explanation of what Percocet is that reads a little more common sense than the language we were looking at before. Can you tell us what a medication guide is, to your understanding, what it's intended for?

A. So, a medication guide is aimed at the patient or the patient's family members; whereas, the other portion was aimed at clinicians, doctors, et cetera, the medication guide is aimed in more -- in simpler language. So, aimed at the patient, or the patient's family members, or associates.

Q. And just focusing on these two bullets, it says Percocet is, and then, one, a strong prescription pain medicine that contains an opioid narcotic that is used to manage pain severe enough to require an opioid analgesic and for which treatments are inadequate and when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.

Is that talking about where the medicine is supposed to be used?

A. That's exactly what it's doing, yes.

Q. It then says an opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed, you are at risk for opioid addiction, abuse and misuse that can lead to death. Do you see that?

A. I do.

Q. And, again, just recognizing that these documents change over time, is it your understanding that that's what this medication guide now tells patients?

A. That is my understanding, yes.

Q. All right. That's what I wanted to cover with you on that document.

I want to switch gears a little bit and pick up on a concept that we've heard about, we've sometimes heard referred to as gateway. In your experience, are there patients you know of or individuals you know of who have misused prescription opioids at one point in time and then later misused heroin?

A. Yes, there are.

Q. Can you comment on how common that is in patients you have treated?

A. So, that's been -- that's been quite rare in patients I've treated. For example, that has not happened a single time in a patient where I -- that I'm aware of in a patient that I initiated opioids, but I have seen it happen in patients who I have been involved in the treatment where other -- other physicians had initiated the opioids.

Q. Are you aware of scientific literature that speaks to that question and tries to analyze that question?

A. Yes, I am.

Q. I want to show you one article on that as an example,

DEF-WV-2331.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

Q. Is this an article -- the lead author is Muhuri, M-u-h-u-r-i -- that you have reviewed in connection with your medical practice and in the context of your work in this case?

A. Yes, it is.

Q. Let's start with the title. The title says Associations of Non-Medical Pain Reliever Use and Initiation of Heroin Use in the United States.

So, I want to just break that down for a little bit. That reference to the word associations, do you have an understanding of what an association is?

A. Yes. That statistically, do the two things go together? What's the rate with which they go together?

Q. From your understanding of medical literature, does the fact that two things statistically go together mean you know there's causation from one to the other?

A. No, it does not.

MR. ACKERMAN: Your Honor, just with respect to displaying the document on the board during our -- the plaintiffs' case, we were precluded from putting documents on the board that had not been admitted into evidence. So, I assume that same rule applies with respect to defendants.

They objected on numerous occasions to our attempts to put documents on the board.

THE COURT: Well, I --

MR. SCHMIDT: I think that's gone both ways, but this is a medical treatise.

THE COURT: I'm sorry, Mr. Schmidt.

MR. SCHMIDT: I talked over the Court. I apologize.

THE COURT: Well, you were very rarely precluded from displaying the documents. It was -- it was whether they could be -- as I recall, whether they could just be displayed before the witness testified, but I consistently allowed you to display documents during the -- to illustrate the witness's testimony, as I recall.

MR. ACKERMAN: With respect, Your Honor, I think there were numerous witnesses where defendants objected to us putting documents on the board. Personally, I put up Dr. Mohr. Defendants objected in entirety to us putting documents on the board and we were not permitted to do so.

Of course, it's within the discretion of the Court, but I want to make sure that objection is stated for the record.

THE COURT: Well, this is technical and complicated testimony and it's helpful to the Court to have these documents available. I'm going to overrule the objection and let you go ahead.

MR. SCHMIDT: Thank you, Your Honor.

BY MR. SCHMIDT:

Q. So, sticking with the title, it refers to something called Non-Medical Pain Reliever Use and then, just for ease of tracking, it defines that down below as NMPR, non-medical pain reliever use. What is that?

A. So, non-medical pain reliever use is when a patient takes an opioid pain medication but doesn't take it for a medical reason, doesn't take it for relief of pain, takes it essentially in the categories we talked about of abuse, misuse, et cetera. So, if they're taking a prescription opioid, but they're taking it to misuse or use it, they are not taking it to treat a medical condition.

Q. So, just to be clear I have that, when this article is looking at associations between pain reliever use and heroin, is it looking at people who are using their medicines as prescribed or misusing prescription opioids?

A. It's specifically looking at patients who are misusing the prescription opioids.

Q. And do you have an understanding as to whether that's the focus of the medical literature in this area when it was looking at the link between prescription opioids and heroin, it was focusing on misuse of prescription opioids?

A. That's my understanding, yes.

Q. Let's look at the abstract, the summary of the study,

and if we could look a little further down, there's a reference that says pooling data from the National Survey on Drug Use and Health, and it summarizes that as NSDUH, conducted annually from 2002 through 2011. Do you see that reference, the data source for the study?

A. I do.

Q. Are you familiar with that data source?

A. Yes, I am.

Q. Could you just give us at a high level what it is?

A. So, it's a large national survey that tries to track the rate of drug use, abuse, misuse, et cetera, among Americans.

Q. And then the sentence finishes, the study finds that the recent 12 months preceding interview heroin incidence rate was 19 times higher among those who reported prior non-medical pain reliever use -- and if we scroll down just a little bit -- then among those who did not, and it gives the statistics, .39 versus .02 percent. Do you see that?

A. I do.

Q. And if we scroll a little further down in the abstract, it says --

MR. SCHMIDT: And can you actually get us the sentence before, as well, Mr. Reynolds? Is that possible? Oh, wonderful.

BY MR. SCHMIDT:

Q. It says, however, the vast majority of NMPR, non-medical pain reliever users, have not regressed to heroin use. Only 3.6 percent of NMPR initiates had initiated heroin use within the five-year period following first NMPR use.

At the risk of asking you to state the obvious, can you tell us what this 3.6 percent figure indicates?

A. Sure. So, their finding is that for patients who started misusing, abusing non-medical pain reliever, abusing, misusing opioid pain medications over the subsequent 5 years, 3.6 percent of those people did then go on to initiate heroin use and the remainder did not.

Q. Okay. So, I'm going to -- if I may, I'm going to ask you about two sets of statistics from this study. The first is the one we just talked about. And I want to make sure I have this right. That 3.6 percent figure, does that address people who misuse prescription Rx opioids and go on to use heroin?

A. Yes, it does, over the subsequent five years.

Q. And just -- you might still have the publication in front of you. Can you tell us again, just from the board, what that percentage is of the people who misuse prescription opioids and go on to use heroin?

A. 3.6 percent.

Q. Are you aware of whether the study also looks kind of

at it from the other end of the spectrum, among the people who used heroin, how many of them have previously misused prescription opioids?

A. Yes. So, it's about 80 percent of the people who used heroin had previously misused or abused prescription opioids. I think it's 79. -- 79.5 percent.

Q. Okay. That's where I'll go to next. So, just so we have it clear for the record, on the right-hand side of the board we have the number of people who misuse prescription opioids and go on to heroin, and that's 3.6 percent. And then, on the left-hand side of the board, we have the people who use heroin. What have they previously used? That's what I'm going to ask you about, okay?

A. Okay.

Q. And you've already told us about this, but is there data in this study on that question?

A. There is.

Q. So, let's look at that data. Probably the easiest way to do it is to go to Page 11, please. And if we look at Page 11, Table 3 is entitled Percentage Distribution of Past Year Heroin Initiates aged 12 to 49. And let me just pause there.

Is this telling us, actually, by demographic and geographic characteristics and prior illicit drug use status? Do you see that?

A. I do.

Q. Is this giving us data looking at people who have started heroin between 12 and 49 in the past year and some of their characteristics?

A. Yes. That's exactly what it's telling us.

Q. And if I look at this table, at the top in the orange or red area, it says Percent Distribution. And then it's got different time intervals, 2002-2004, et cetera, all the way up to a full range of years, 2002-2011. Do you see that?

A. I do.

Q. And I'm going to focus on the full range of years. I'm not sure it's materially different, but let me just capture the fullest dataset, 2002-2011, and I want to show the Court that statistic you were talking about.

So, if we stay on that far right column and go all the way down to the bottom of the page, do you see at the bottom of the page they break the group of heroin users they surveyed out between those who had no prior non-medical pain reliever use and those who had prior medical pain reliever use?

A. I do, although it's prior non-medical pain reliever use.

Q. Oh, I might have misspoke. Okay, sorry. And do you see the statistic you told us about in terms of the

percentage of patients who -- the percentage of people who -- I'm sorry. Let me start my question again.

Can you tell us the statistic in terms of the number of people who used heroin in the last year and then, at some point prior to that, had non-medical pain reliever use?

A. Yes. So, 79.5 percent of the people in this age group who initiated heroin use in the -- in the leading to -- in the prior 12 months, 79.5 percent of them had engaged previously in non-medical pain reliever use.

Q. Okay. Is that the same as misuse of prescription opioids?

A. That's the same as misuse and abuse of prescription opioids.

Q. Is that a meaningful statistic?

A. Yes, it is.

Q. We see in this study that it is using data up through 2011 according to the heading. Have you considered -- have you continued to see data like this published more closely in time to today?

A. Yes, I have.

Q. Broadly speaking, do you know whether this number has stayed the same, gone up, gone down?

A. Broadly speaking, that number actually has gone down. There are more of the people who have initiated heroin use who actually have not previously misused or abused

prescription opioids in more recent times.

Q. Okay. So, I want to stick with this portion of the article we have up on the screen and under the heading we've been talking about --

MR. SCHMIDT: And, Mr. Reynolds, I think you've actually got the wrong percentage highlighted. It should be the bold 79.5 percent.

BY MR. SCHMIDT:

Q. Under the heading that tells us prior NMPR use and then we see 79.5 percent, the number we have up on the board, do you see that?

A. I do.

Q. In the sub-columns do you see the reference to prior illicit drug use?

A. I do.

Q. All right. And I want to ask you what that means and then ask you what that data tells us. Do you see the little footnote marker number 2 there?

A. I do.

Q. If we turn to Page 12 of the article, do you see that it defines what Footnote 2 is, what illicit drugs are?

A. I do.

Q. And could you just read into the record what those are?

A. So, it says illicit drugs include marijuana, hashish, cocaine, including crack, hallucinogens and inhalants.

Q. So, I've written on the board marijuana, cocaine, crack, other illegal drugs. And so, having that on the board --

MR. SCHMIDT: If we could go back to the bottom of Table 3 on Page 11 of the document, please.

BY MR. SCHMIDT:

Q. Under the bold heading Prior Non-Medical Pain Reliever Use, Prior Misuse of Prescription Opioids, do you see where they break out people who had no prior illicit drug use and people who did have prior illicit drug use?

A. I do.

Q. And can you tell us from looking at that data what percentage of heroin users in this study had both prior non-medical pain reliever use and prior illicit drug use?

A. So, for prior illicit drug use, it's 79.5 percent.

Q. And then, I want to look at the heading above, looking at the patients who have no prior non-medical pain reliever use. Do you see that heading?

A. I do.

Q. And do you see below that where it tells us the patients -- the percentage of the pool who have no prior non-medical pain reliever use, but who have prior illicit drug use, what percentage that is?

A. That's 19.4 percent.

Q. I'm going to ask you what I hope is my toughest

question. I've already shown myself today to be unreliable at math.

Can you tell us what these two numbers add up to in terms of the number of heroin users who have some prior illegal drug use?

A. So, 98.9 percent.

Q. So, a couple questions about that data and how it meshes with your experience. First of all, this article gives us data on people who misuse prescription opioids. It gives us data on people who misuse illegal drugs like crack cocaine and cocaine and other drugs. Are there other factors relevant to substance abuse that may or may not be reported in this article, may not be captured in this data?

A. Yes, there are.

Q. Could you speak with us about some of those factors?

A. So, those are the factors that we talked before of a family history of substance abuse, major psychiatric illnesses such as Bipolar Disorder, et cetera, even demographic factors, age, gender, et cetera, et cetera, that predispose somebody to be at risk for substance abuse, misuse, et cetera. Those factors apply here, as well as the statistics that we're talking about.

Q. Now, focusing on these two numbers here and drawing on your medical experience and your understanding of the science, are you able to say whether of these people who

used heroin, who had previously misused prescription opioids, whether if you took away that prescription -- misuse of prescription opioids, but still had the other factors, the 98.9 percent who are abusing illegal drugs and then the other factors you just alluded to, whether that would change the heroin rates, do you know?

A. You can't say.

Q. And why is that?

A. Because even if you took away the misuse and abuse of the prescription opioids, all of those other risk factors, there are folks who already are engaged, 98.9 percent of them, in use abuse, misuse of illicit substances. So, by definition, they're engaged in that and would be at risk of additional substance abuse, including heroin abuse and misuse.

Q. Can you say looking at this data whether this is a problem that's isolated to the misuse of prescription opioids, as opposed to a broader substance abuse problem?

A. So, it's a broader substance abuse problem where, in some patients or in some individual's case there is misuse and abuse of prescription opioids, but it's a broader substance abuse problem.

Q. Let's conclude with that topic. I want to go back to what we were talking about in terms of benefit and risk. We've spent a lot of time talking about risk, pretty serious

risk. Given those risks of prescription opioids, why is it that doctors still use prescription opioids?

A. So, the reason that doctors still use prescription opioids despite those risks that we've talked about, which are significant, is that they're our most potent pain medications and there are some cases where patients have severe disabling pain that we can't treat successfully and/or safely with non-opioid treatments.

And so, there's some patients where it clearly does add up in terms of risk benefit to treat them with the opioids and, as we talked about before, there's some patients where those risks we can identify as being substantially lower for that patient. So, in the end, that risk benefit does fall squarely on using opioids to treat that patient's case.

Q. You talked earlier about your clinical research, your scientific research. Have there been efforts in the scientific community over time to come up with alternatives to prescription opioids that would be as effective at treating pain without having these risks we've been talking about?

A. Yes. Identifying a very powerful non-opioid pain medication that's safe and has no risk of addiction has essentially been a holy grail of our field.

Q. Have pain management found that holy grail?

A. Not -- not yet.

Q. Okay. Let me talk about data for a little bit on prescription opioids. Are you familiar --

THE COURT: Is this a good place to stop? It's about break time, Mr. Schmidt.

MR. SCHMIDT: Sure. Yeah. Yeah.

THE COURT: Let's be in recess for about ten minutes.

You can step down, Dr. Gilligan.

THE WITNESS: Thank you, Your Honor.

(Recess taken)

(Proceedings resumed at 10:37 as follows:)

THE COURT: When you're ready, Mr. Schmidt.

MR. SCHMIDT: Thank you, Your Honor.

BY MR. SCHMIDT:

Q. Dr. Gilligan, I want to pick up with where we were by talking about the benefits of these medicines.

You talked a little bit about the search for alternatives. And I wanted to talk to you a little bit about, in broad terms your understanding of the data regarding these medicines.

Are you aware of studies showing that opioids are effective for treating acute pain?

A. Yes, I am.

Q. And what -- can you speak to what the data shows in terms of using prescription opioids to treat chronic pain?

A. So for chronic pain, the data with chronic opioid therapy is, frankly, more mixed. There are studies that show that if you use chronic opioid therapy for non-cancer pain cross a population in the study, in some studies that you don't see an improvement in function, or even a subset is you don't see an improvement in pain. Some show improvement. Some don't. And the studies show high rates of harm, of adverse effects from chronic opioid therapy for non-cancer pain.

Q. So does that mean that doctors today never use prescription opioids for chronic non-cancer pain?

A. No, it does not.

Q. So can you explain that -- can you reconcile that for us? Why are doctors using it if the study data is mixed?

A. So if the study data is showing across a population in a study you're not seeing an improvement in function, in some cases in pain in many of those studies, but there are certain individual patients who do do very well.

So it's the difference between an individual patient if you select someone who has low risk for developing problems with addiction who has a condition that you're being very selective, the indication for using it for that condition is really quite strong and the benefit, or the potential benefit for that patient is quite high. It's the difference between there are some individual patients who do very well

versus what you see when you look at a population in a study on average.

Q. Do you understand that view you just expressed that there are individual patients for whom prescription opioids are appropriate for chronic non-cancer pain, do you understand that view to be the consensus of the medical community?

A. Yes, I do.

Q. For example, are you familiar with CDC guidelines that have come out in the last several years regarding the use of prescription opioids in chronic non-cancer pain?

A. Yes, I am.

Q. And do they allow for or recognize that for some patients using prescription opioids for chronic non-cancer pain is appropriate?

A. They do. They spell out what are the circumstances where it would be appropriate to do it. They spell out how to do it judiciously and cautiously. They spell out guidance on what types of doses to use, et cetera, how to monitor patients.

But the whole point of those guidelines implicit in them is that they are giving you guidance on when and how to appropriately use opioid pain medications for chronic non-cancer pain.

Q. Dr. Gilligan, there's been discussion in the case

about -- a little bit of discussion in the case about prescribing levels of opioids in the United States versus other countries.

Do you have experience in your medical practice with use of prescription opioids in countries where they're much more restricted and conservative in using prescription opioids?

A. I do.

Q. Can you tell us about that experience?

A. Sure. So in one of my roles at the Brigham is that I'm the Medical Director for an affiliation that we have with a cancer hospital in China. And in China, the use of opioids for cancer pain and for non-cancer pain is far, far more conservative than it is in the United States.

Q. And how do you see that play out in your experience in terms of patient care?

A. So there are some patients who we see there who -- their pain is -- could be safely and much more effectively controlled if opioids were used in their cases and in the way that we would use it; in other words, cautiously judiciously but appropriately.

We see some patients who in our judgment are, for example, dying of cancer and suffering from very, very severe pain that we think could be more effectively and safely treated with opioids.

Q. We've been talking about the risks and benefits of opioid medications. Do you have a view as to who in the healthcare system is best situated to counsel patients on those benefits, on those risks?

A. I do.

Q. Who is that?

A. I think clinicians, principally doctors, because our education is to have abundant knowledge about the conditions and the medications and their risks and the potential benefits.

Our training is training us to make those judgments, how to take in that information and take it in, weigh in, you know, what's high quality information, what's low quality information that you should tend to discount, et cetera.

And then for these controlled substance prescription medications, that's the, the authority that we get when we get DEA certification, medical license, controlled substance certificate, et cetera, that is both giving us that authority to make a prescribing decision.

And the accompanying oversight bodies in our field are also there for in case a physician stops prescribing appropriately. And that can be at the level of the hospital, at the Board of Registration of Medicine, could be the DEA pulling somebody's certificate, et cetera.

So everything about our education, training, role, authority, and then responsibility and monitoring is, is matched to our role in making those decisions.

Q. I want to pull out some of those points you just walked us through in a little more detail if I could.

Let me start with, with the first part of what you said for us. In terms of access to medical records, access to the patient, is, is there anyone or entity in the healthcare system that has more visibility to the patient than the doctor or other clinicians who's treating them?

A. No, there isn't because we're the one who's in the exam room. We're taking the patient's complete relevant medical history and demographic history, et cetera. We're examining the patient. We're looking at the results of any relevant test, X-rays, MRIs, lab tests, et cetera. The other -- at least I can't think of another party that has that level of information specific to that patient.

Q. Uh-huh.

A. And these decisions are all about the individual details of that individual patient's case. That's the essence of, of making those decisions appropriately and correctly in individual cases.

Q. As a physician, are you bound by both legal responsibilities regarding your patient and ethical responsibilities?

A. Yes, we are.

Q. And do you have a view whether it would further those legal and ethical responsibilities if you were caring for your patients and making judgments for your patients other participants in the healthcare system like distributors were second-guessing those judgments?

A. I, I don't think that that would be helpful for our patients. I don't think that would be helpful for society. I do not think that that would help to make the decisions be done more appropriately.

Q. You, you talked about some consequences in your answer a few moments ago for doctors who don't practice within those standards. You were talking about including losing their ability to practice, maybe going to jail. And we've heard some examples of that.

But short of losing a license or criminal action, are there other controls in your experience that apply to doctors who are inappropriately prescribing?

A. Yes, there are.

Q. Can you tell us about some of those?

A. So when we have concerns within our healthcare system about a physician's prescribing, we'll step in and we'll monitor that physician's prescribing. We will, for example, pull 25 charts per month from that patient, that physician's patients and review those records and look at the records

and say were the prescribing decisions in each of those cases made appropriately or not.

We'll do didactic education sessions sometimes one on one with that physician and other things along those lines.

Q. And you just in giving that answer referred to yourself in the first person plural. Have you been involved in that kind of review of other physicians' prescribing practices so you can make judgments about whether it's appropriate or inappropriate?

A. Yes, I have.

Q. Is that something you're able to do just by looking at prescribing records and prescribing levels or, or do you need more patient information?

A. When I do that and when we do that in general, we need the patient level information because you can't determine if a given prescribing decision was appropriate or not unless you get the relevant information; in other words, what was the patient's history, what were the findings on exam, what did the tests show, what other therapies were tried, et cetera, to make that determination about that case.

Q. Okay. Does making that determination require you to exercise medical judgment based on your medical training?

A. Yes, it does.

Q. I'm going to turn to our last topic. It's a larger topic. It might take us close to lunch or just shy of

lunch. And it's, it's a concept that we've heard referred to as standard of care. Is that a concept you're familiar with in medical practice?

A. Yes, it is.

Q. Can you tell us what that means in terms of medical practice?

A. So standard of care in medical practice means the quality of care, the thoroughness, the safety of care that doctors expect to maintain in his or her fields. Sometimes there's a geographic component to it, you know, in practicing in your field and in the area where you practice, what you would be expected to do. And that can apply to anything. That can apply to the -- what you should be expected to have done if somebody came in with a potential heart attack.

Q. I want to focus on prescription opioids. Are you aware of whether the standard of care regarding prescription opioids has changed over the past several decades?

A. Yes, it has.

Q. And at a high level can you walk us through that change?

A. So in the period around the 1990s in particular, a little bit in there, 1980s as well, there was an emphasis on the concept that we were under-treating pain in this country and that we were placing too much emphasis -- that we were

exaggerating, would have been the argument, the potential risks of opioids, that we were under-utilizing them and we were leaving too many patients with pain that could have slash should have been treated with opioids.

Then as prescribing went up by about certainly I think roughly the mid 2000s, there was much more awareness of the adverse effects and the argument that perhaps we were prescribing too many opioids as opposed to too few, and that we were -- that we should put more emphasis on the potential risks of the medication.

Then around 2011 prescribing in the country peaked and started to go down. And since then, there's been significant emphasis on the, the risks of these medications, potential risks, the fact that there are some patients with chronic non-cancer pain, for example, who don't get significant benefit where -- while there are some people who do.

And, so, an emphasis on still using the medications but being more conservative about them as part of the standard of care.

Q. Okay. We, we've heard evidence in this case about prescribing rates in Cabell County, West Virginia. And I want to just ask you if that's consistent with what you just told us.

The evidence is prescribing rates increased in the late

'90s up until a peak in about, between 2010, 2012, that range, and then have gone back down. Is that consistent with those changes in the standard of care that you told us about?

A. Yes, it is.

Q. Is it consistent with your understanding of national prescribing trends in terms of increasing from the '90s up until sometime in the 2010, 2012 window and then coming back down?

A. It is.

Q. All right. I'd like to show you some documents relevant to the standard of care issue and the changes in the standard of care that you talk about in your report.

Let me start, if I could, with MC-WV-1135.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

MR. SCHMIDT: Thank you.

BY MR. SCHMIDT:

Q. And just to orient us, this is a publication from the New England Journal of Medicine. Are you familiar with that publication?

A. Yes, I am.

Q. It's dated January 14, 1982. Can you just characterize for us the role that the New England Journal of Medicine plays in the practice of medicine?

A. It's, it's one of the most respected medical journals that there is.

Q. And if we look a little further down, there's an editorial called "The Quality of Mercy." Do you see that?

A. I do.

Q. Are you familiar -- have you, have you read that editorial that's actually attached there?

A. I have.

Q. If we go to Page 3 of the document -- we've skipped the full journal but just focused on this editorial. It's written by someone named Marcia Angell. Do you know if she had a role at the New England Journal of Medicine at this time?

A. Yes. She was a Deputy Editor at the New England Journal at this time.

MR. SCHMIDT: Your Honor, we'd move this document, MC-WV-1135, into evidence.

MR. FARRELL: Judge, this is a medical article, medical literature, and I don't know that it's appropriate to admit it into the record as evidence. And to the extent that it's being offered for notice or some other reason, I just don't think it's appropriate from the historical rulings this Court has made about admitting medical literature.

MR. SCHMIDT: Your Honor, just to be --

MR. ACKERMAN: Your Honor, may I add --

THE COURT: Yes.

MR. ACKERMAN: -- to my colleague's statement?

To the extent that defendants are relying on 803(18) as the exception to the hearsay in the document, that exception does not permit the admission of statements in a learned treatise, but only permits that a statement in a learned treatise may be read into evidence but not received as an exhibit.

MR. SCHMIDT: Your Honor, just to orient the Court, what we're actually moving it in under is 803(16), 16, statements in ancient documents, which I find that expression a little hurtful. It's a statement in a document that was prepared before January 1st, 1998, which this was, and whose authenticity is established. And this is a self-authenticating document under Rule 902(6).

MR. FARRELL: Judge, I vehemently object to the reference of the year 1998 as being ancient.

MR. SCHMIDT: I join.

THE COURT: Well, you've got a point, Mr. Farrell.

MR. FARRELL: So, in general, Judge, I know this article. We've talked about this article. I understand the article. I support the article. I know the New England Journal of Medicine is a leading text. And I also know the point Mr. Schmidt is going to make.

I'm simply saying that we haven't been admitting medical learned treatises into the record, but we have liberally been using them and referencing them with experts throughout this trial.

So I have no problem with referencing it or talking about it. I'm looking forward to the testimony. I just -- I don't want to start the, the onslaught of admitting medical literature as learned treatises or antiquities into the record.

MR. SCHMIDT: I think the difference here is the clear exception in Subsection (16). It's, it's pretty black and white.

THE COURT: Well, --

MR. FARRELL: Perhaps, Judge, if it was offered for the limited purpose of notice or limited purpose, something other than a learned treatise because if we're going to start admitting learned treatises, I have a book of learned treatises and articles that we wish we would have admitted during our case-in-chief.

MR. SCHMIDT: I think if they can come in under 803(16), they could do that. It's a pretty specific rule.

THE COURT: It's certainly admissible under 803(18) but it can't be admitted if -- we'd have to have him read it if we did that.

MR. ACKERMAN: And, Your Honor, the part that

troubles me, and I will be frank with you that I never looked into this, is how 803(16) could work to obviate what appears to be a more applicable exception in 803(18).

MR. SCHMIDT: By its language, a statement in a document that was prepared before January 1st, 1998, and the authenticity is established.

THE COURT: Well, it comes within the literal reading of (16), doesn't it, Mr. Ackerman?

MR. ACKERMAN: I think it does, Your Honor. I don't dispute that.

THE COURT: I'm going to admit it under 803(16) --

BY MR. SCHMIDT:

Q. So let's --

THE COURT: -- for the truth of the matter asserted.

BY MR. SCHMIDT:

Q. Let's look at Page 2, please, of this publication, "The Quality of Mercy." You'll see that up there at the top. And I just want to read a couple lines to you.

It says, "Few things that a doctor does are more important than relieving pain."

Let me pause there. Is that a view you agree with based on your medical practice?

A. Yes, it is.

Q. "Yet, the treatment of severe pain in hospitalized

patients is regularly and systematically inadequate."

Do you see that?

A. I do.

Q. And we're back in 1982 at this point in time. Was this a view that started to be expressed in the medical literature at this point in time?

MR. FARRELL: I'm going to make an objection, Judge. If we're going to admit this, then we should admit it for what it is. This isn't medical literature. I believe this is an editorial.

MR. SCHMIDT: I'll rephrase.

BY MR. SCHMIDT:

Q. Is that a view that started to be expressed in the medical community through various sources at this point in time, that the treatment of severe pain in hospitalized patients is regularly and systematically inadequate?

THE COURT: Overruled. I'll let him answer that question.

THE WITNESS: Yes, it is.

BY MR. SCHMIDT:

Q. It goes on to say -- it quotes some data. And then in the sentence after quoting that data it says, "This is not for want of tools. It is generally agreed that most pain, no matter how severe, can be effectively

relieved by narcotic analgesics."

Do you see that?

A. I do.

Q. And, again, are you familiar with the point that there started to be a movement in the medical profession to do more to treat pain and recognized opioid analgesics as part of that?

A. Yes.

Q. And, so, where I'm going to go with this --

MR. SCHMIDT: And I'm going to pass out the completed version that we sent last night. We, we have given counsel a demonstrative we're going to use. We'll print out a copy, but you should have it from last night. And we'll give out more when we're done. We're going to build it with some of these articles.

Can we go to that please? I'm just going to track some of these sources up on a board that we're going to see. And I'm going to make a confession right at the outset. We had trouble figuring out our timeline at the bottom.

So you'll see there's just years here along the bottom and it's not to scale. We start with the '80s and then jump all the way to the '90s and then kind of slow down a little bit in the '90s.

But if you'll bear with me with that, I'm going to put some of these up on the board.

So can we start by putting this article up on the board?

BY MR. SCHMIDT:

Q. Is that that quote we were just looking at from the New England Journal of Medicine about, "It is generally agreed that most pain, no matter how severe, can be effectively relieved by narcotic analgesics"?

A. It is, yes.

Q. All right. Let's go back to the article itself. We'll come back to this board as we look at other publications and documents.

If we scroll down into the next paragraph, it says, "One consideration that limits the use of narcotics is the possibility of a variety of side effects."

And then it lists several including drowsiness, constipation, urinary retention and, most serious, respiratory depression.

"A more important factor is a disproportionate sometimes irrational fear on the part of the medical profession and the public alike that patients will become addicted."

Do you see that?

A. I do.

Q. And are you familiar with that view being expressed by doctors at this point in time going forward that there might

be a disproportionate, sometimes irrational fear, on the part of the medical profession and the public that patients will become addicted?

A. Yes, that was one of the views that was being put forth at that time.

Q. And let me just jump to the end of this article, if I could, back to the author. I asked you earlier about Marcia Angell. Is she someone who has standing in the medical profession?

A. Yes. Dr. Angell was, was very respected.

Q. Did she have a reputation one way or another in terms of her attitude towards drug companies and manufacturers?

A. Yes. She was well-known as really a fierce critic of the for-profit pharmaceutical companies.

Q. Okay. Let's look at some other things that -- if we could look at that paragraph you pulled up. It states, "It is instructive to contrast the very low incidence of important side effects with the very high incidence of inadequate pain relief. I can't think of any other area of medicine, in medicine in which such an extravagant concern for side effects so drastically limits treatment. We are used to a closer balance between risks and benefits."

Do you see that?

A. I do.

Q. And can you just comment on that statement,

particularly this statement at the end about risk and benefits?

A. So Dr. Angell is making the point that we discussed before that -- which was a point that was made at this time period that the perception was we're not -- we weren't treating pain aggressively enough and we were exaggerating our understanding of the risks.

And, therefore, by definition then that would get your risk benefit calculation off if you accept that argument.

Q. And then let's just go to the end of, of this article.

"Pain is soul destroying. No patient should have to endure intense pain unnecessarily. The quality of mercy is essential to the practice of medicine; here, of all places, it should not be strained."

Do you see that?

A. I do.

Q. And how does that fit with your experience in pain treatment and pain management?

A. I think actually she wrote that very, very well. I think pain is soul destroying. I think that you wouldn't want to see a pain -- a patient having to endure intense pain unnecessarily. And I think that the quality of mercy is essential to the practice of medicine.

Q. We've, we've walked through a series of statements in this editorial. Is it meaningful if an editor at the New

England Journal of Medicine makes statements like this to the medical profession?

A. Yes. This is a -- the New England Journal of Medicine, as we've discussed, is one of the most respected medical journals. Dr. Angell was a very well-known and respected figure. And, so, a statement like this has a significant impact on, on physicians.

Q. I'd like to approach with another document, if I may, Defense West Virginia 3699. I've given you a copy of a document entitled Cancer Pain Relief. And below the heading you see a crest and it says it's from the World Health Organization in Geneva. Do you see that?

A. I do.

Q. And then if we just flip ahead to the third page, it again repeats the title, Cancer Pain Relief, World Health Organization, 1986. Are you familiar -- are you familiar with this document I've just handed you?

A. Yes, I am.

Q. Can you comment on the significance of this document in pain management?

A. So this document was very, was very significant because it's the document where the World Health Organization introduced their cancer pain treatment letter which became very well-known throughout medicine and, and had a very significant influence on the practice of treating pain

across fields of medicine.

MR. SCHMIDT: Your Honor, we move into evidence Defense West Virginia 3699 under the ancient documents exception.

MR. ACKERMAN: I'd renew our objection, Your Honor. I would just note that the Advisory Committee Note, which Ms. Kearse has helpfully provided me, to Rule 803(16) references letters, records, contracts, maps, and certificates.

So I think -- again, it's our position that the ancient document exception was not intended to apply to learned treatises which are referenced in another section.

MR. SCHMIDT: The language, just for the record, that's being referenced is, "Wigmore further states that the ancient document technique of authentication is universally conceded to apply to all sorts of documents." And then it says "including the examples listed."

MR. RUBY: And, Your Honor, I know Mr. Schmidt doesn't need my help, but with respect to Mr. Ackerman's reference to the term "record," there are definitions, of course, in the Rules of Evidence.

And in Rule 101(b)(4) record is defined to include a memorandum or report which certainly would include this document.

THE COURT: I'm going to admit it. It's admitted.

West Virginia 3699 is admitted.

BY MR. SCHMIDT:

Q. So let's look at what was important about this document. And I'd like to, again, using the numbers in the bottom left corner of the page, if we can go to Page 10, please. And there's a heading "Nature of Cancer Pain." I'm actually going to look at the paragraph right above that.

So now we're up to 1986. This tells us numerous published reports indicate that cancer pain is often not treated adequately.

Again, is that consistent with some of these discussions from this time period now up to 1986 about doing more to treat pain; in this case, cancer pain?

A. Yes, it is.

Q. "An analysis of 11 reports covering nearly 2,000 patients in developed countries," and they emphasize that, "suggests that 50 to 80 percent of patients did not have satisfactory relief. Many patients with advanced cancer and moderate to severe pain are not given sufficient analgesic medication to control their discomfort."

Are you familiar with that kind of data from this time period showing that patients who had cancer pain weren't given satisfactory relief?

A. Yes, I am.

Q. It says, "They are restricted to a weak opioid (e.g. codeine) or a stronger drug is given on demand instead of being given at appropriate regular intervals by the clock."

Then they talk about developing countries and that data there.

And then the final sentence says, "It seems certain, however, that most patients do not receive adequate therapy because of legal and other constraints on access to drugs and notably to the strong opioids."

Do you see that?

A. I do.

Q. And, again, was that a sentiment that was being expressed at this time that legal and other constraints on prescription opioids were depriving patients of effective pain relief?

A. Yes. A constraint such as that and exaggeration of concerns that we talked about from other, that was on other documents were leading clinicians to under-use and -- under-use opioid pain medications and to under-treat pain.

And, essentially, the argument at that time was that they -- clinicians were typically getting the risk benefits wrong and not treating pain aggressively enough, not using opioid pain medications enough.

Q. Let's go to Page 50, if we could, of this document. It says, "Reasons for inadequate control of cancer pain."

And if you look at the -- I suppose it's the last sentence here, it refers to a misconception by doctors, nurses, and patients to the effect that physical dependence and psychological dependence are interchangeable terms has led to the under-use of opioid analgesics."

Do you see that?

A. I do.

Q. Is it meaningful when the World Health Organization is making a statement like that about under-use of opioid analgesics?

A. Yes, it's very meaningful.

Q. Okay. Let's go to the board, if we could, and we'll just add that quote under use of opioid analgesics, 1986.

Why is it meaningful that the World Health Organization, WHO, is saying what with reference to cancer pain?

A. Because doctors know the World Health Organization. You would be hard-pressed to find a doctor who doesn't know the World Health Organization. And when they make a statement that's that clear saying that we're under-treating cancer pain and we should use opioids more often, more aggressively to, frankly, do a better job of treating cancer pain, that's a, that's a powerful statement coming from an organization of that stature.

Q. Okay. Let's go back to the document. I want to jump

ahead now to Page 20.

And we see a heading on the side, on the page that says "Drug Therapy." Do you see that?

A. I do.

Q. It says, "The use of analgesic drugs is the mainstay of cancer pain management."

Does that remain true to this day?

A. That remains true to, to this day, yes.

Q. It says, "When used correctly, analgesics are effective in a high percentage of patients. A three-step analgesic ladder is suggested (see diagram opposite)."

And then if we look at Page 21 -- let's just cull up this diagram that they're referencing.

Are you familiar with this diagram?

A. Yes, I am.

Q. Have you heard it sometimes referred to as a pain ladder?

A. Yes, that's what we commonly refer to it as, the World Health Organization pain ladder.

Q. Can you just walk us through -- I see one, two, three and then references to different types of pain and treatments. Can you walk us through what this pain ladder is communicating?

A. So it's communicating to doctors and other clinicians that when you encounter a patient with cancer pain, you

start with a non-opioid and associated adjuvant medication. If that gives the patient relief, you are typically going to stop there. If it doesn't, you go up to the next level, the next rung.

And if pain is persisting or increasing, at that point it's recommending that you start a weak opioid plus those non-opioids plus those adjuvant medications. Again, if that works, you're typically going to stop there.

But that if the pain persists or increases, you will then go up another rung. And now you'll go to strong opioids, as well as those non-opioid medications and adjuvants.

And you can see at the top that your goal is to achieve for that patient freedom from cancer pain.

Q. And picking up on that goal, freedom from cancer pain, did there come a time where the concepts reflecting this ladder, stepping up based on the pain and what worked and didn't work, were applied more broadly in the medical profession in cancer pain?

A. Yes. Over time the same -- this had an influence, of course, on cancer pain. But also it started to have an influence on treatment of pain including non-cancer pain.

Q. Okay. Let's go back to the timeline, if we could, and again recognizing this is horribly not to scale. But in 1995 you put Oxycontin on there.

Are you familiar with the FDA's approval of Oxycontin in 1995?

A. Yes, I am.

Q. Do you have an understanding as a clinician why it was approved?

A. My understanding it that it was approved in line with the same approach of trying to have more, more therapies available, more long-acting opioids available to use to treat cancer pain and non-cancer pain to give clinicians more ways to treat pain.

Q. Do you have an understanding as to whether during that broad time period we're talking about, '80s, '90s, as the medical profession was talking about pain more and opioid analgesics more, the FDA approved several opioids during that time interval?

A. That is correct.

Q. Do you know of any role that distributors play in the approval of prescription opioids?

A. I'm not aware of any role that distributors play in the approval of opioids.

MR. FARRELL: Judge, if I may, since we're using a demonstrative, I don't believe the question has been asked to establish the date or the distinction between approved and launched or sold.

BY MR. SCHMIDT:

Q. Do you know when Oxycontin was approved?

A. It was approved in 1995.

THE COURT: Does that take care of your objection, Mr. Farrell?

MR. FARRELL: Sort of. I also wanted to -- I'll clean it up on cross.

THE COURT: Okay. I'll overrule the objection. I think, yeah, it's a matter for cross.

Go ahead, Mr. Schmidt.

BY MR. SCHMIDT:

Q. Okay. I want to ask you about state medical boards. Are you familiar with state medical boards?

A. Yes, I am.

Q. Do they play a role in, when we talk about standard of care, in setting the standard of care?

A. They do.

Q. What role do they play?

A. So for a doctor to practice, you need your license from your state medical board. And if you were practicing inappropriately, for example, they would be the folks who could pull your license.

So, therefore, as, as a doctor, one tends to pay attention to what the state medical board is calling for in terms of appropriate practice.

Q. Okay. Did there come a time where state medical boards

began to take steps to support broader opioid prescribing?

A. Yes, there did.

Q. As part of your work in this case -- and we've got an expert coming next week who's going to dive into this more, so I'm just going to touch this at a very high level.

But as part of your work in this case, did you track whether some of these changes in the standard of care tracked into guidance documents from the West Virginia Board of Medicine?

A. Yes, I did.

MR. FARRELL: Judge, I'm going to place an objection on the record. As indicated in my *voir dire*, this witness is certainly an expert in the national standard of care, but is not licensed in West Virginia, does not practice in West Virginia, and has no basis in fact to make any comments about the West Virginia Board of Medicine.

MR. SCHMIDT: And, Your Honor, I think the fact that he has general pain management experience, general opioid experience makes him eminently qualified to look at West Virginia Board of Medicine documents and comment on whether they're consistent with --

THE COURT: I agree. I think his expertise has been established to the point where I think he's qualified to look at the West Virginia materials and pass an opinion on -- based on those. Overruled.

MR. SCHMIDT: And I will be brief with this. May I approach, Your Honor?

THE COURT: Yes.

MR. SCHMIDT: Thank you, Your Honor.

BY MR. SCHMIDT:

Q. So just to orient us to what we're looking at, we've put it up on the screen, MC-WV-01219 which is in evidence. It's from the State of West Virginia, West Virginia Board of Medicine. And if we look at the second page at the end, we see it was adopted by the West Virginia Board of Medicine in 1997. Do you see that, Dr. Gilligan?

A. Yes, I do.

MR. ACKERMAN: Your Honor, I just want to note that the document, while in evidence, was admitted for a limited purpose, make that clear.

MR. SCHMIDT: I don't recall if that's correct or not. But if that's true, we don't take issue with that. I didn't have that recollection, but I'm not -- I didn't look at that.

BY MR. SCHMIDT:

Q. So let's go to the second paragraph of this. It says, "The purpose of this statement is to clarify the Board of Medicine's position on the appropriate use of opioids for patients with chronic non-malignant pain."

Let me pause there. What is chronic non-malignant pain?

A. So chronic non-malignant pain is chronic non-cancer pain.

Q. Okay. "Clarifying those standards show that these patients will receive quality pain management and so that their physicians will not fear legal consequences, including disciplinary action by the board, when they prescribe opioids in a manner described in this document. It should be understood that the board recognizes that opioids are appropriate treatment for chronic non-malignant pain in selected patients."

Do you see that?

A. I do.

Q. Is this consistent with this change in national standards that you've been telling us about at this time in the 1997 time period?

A. Yes, it is.

Q. All right. Let's go two lines -- two paragraphs down. You talked about the role that state medical boards play in discipline. Do you remember telling us about that just a moment ago?

A. I do.

Q. It says, "A physician need not fear disciplinary action by the board if complete documentation of prescribing of

opioids in chronic non-malignant non-cancer pain even in large doses is contained in the medical records."

Do you see that?

A. I do.

Q. And if we can go back to the timeline and put that quote on the timeline under 1997.

Just in general terms, what's the import of a statement like that from a, from a State Board of Medicine?

A. So for a doctor, that's a clear message. It's very clearly written saying that if you prescribe opioids even in large doses for non-cancer pain -- and there is a reference that you're going to have to have complete documentation. You're going to have to justify your decision to do that in your medical record which would be for a doctor expected. That in that case, you need not fear disciplinary action.

And that's -- that would typically be quite significant to a physician because disciplinary action from a medical board could mean losing your medical license and not being able to practice medicine, for example.

Q. Are you familiar with something called the Federation of State Medical Boards?

A. Yes, I am.

Q. Could you tell us what the Federation of State Medical Boards is?

A. So it's a group that tends to write guidelines and

documents for -- that are then frequently adopted by medical boards in the different states.

Q. Okay. Are you familiar with publications that the Federation of State Medical Boards has issued over time regarding prescription opioids?

A. Yes, I am.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. I've given you what I've marked as Defense West Virginia 2937. If you look at the top of it -- well, actually, let's look at the second line -- the third line, smaller print.

Do you see in that sentence there's a reference to the Federation of State Medical Boards, and it's dated May, 1998. Do you see that?

A. I do.

Q. And it says, "Model guidelines for the use of controlled substances for the treatment of pain."

Are you familiar with this document?

A. Yes, I am.

Q. At a high level, can you give us an overview of, of what this document is?

A. So it's a document written by the Federation of State Medical Boards spelling out their, their guidelines for the

appropriate use of controlled substances to treat pain.

And then this is the, the -- this sort of document -- indeed, this one was -- the sort of document that many state medical boards would then adopt as their, as their guideline.

MR. SCHMIDT: Your Honor, we missed the ancient records exception by a few months for this document, so I'll take up Mr. Farrell's invitation to move it in just for the limited purpose of notice, Defense West Virginia 2937.

THE COURT: Is there any objection?

MR. FARRELL: No, Your Honor.

THE COURT: It's admitted for the limited purpose.

BY MR. SCHMIDT:

Q. Let's look at some of the language in this document.

First of all, if you go to the third paragraph, please, it states, "The board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain whether due to cancer or non-cancer origins."

Are you familiar with that statement from the Federation of State Medical Boards in 1998?

A. Yes, I am.

Q. And if we go over to the timeline and put that on a timeline, 1998, can you comment on the significance, if any,

of the Federation of State Medical Boards issuing this broader statement including the specific recognition that opioid analgesics may be essential for acute pain due to trauma or surgery and chronic pain whether due to cancer or non-cancer?

A. So it's part of the same change over time and encouraging increase in the -- essentially increase in the aggressive treatment of pain with the, the, this concept that we've been perhaps under-treating pain.

And it's significant that they're spelling out not just acute pain and not just chronic pain due to cancer, but also including chronic pain due to non-cancer origins.

Q. And do you understand this to be consistent with the standard of care regarding prescription opioids as it was developing in this time period?

A. Yes, I do.

Q. Let's go back to the article itself, please, Defense West Virginia 2937. And if we go back to that third paragraph, I just want to cull out some other language at the end.

"Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction."

Can you explain to us what you understand the Federation of State Medical Boards to be saying with that

statement?

A. So what they're spelling out for physicians is -- and I agree with them, by the way -- if, if you prescribe a significant dose of opioids to any patient over a significant time period, that patient will become physically dependent.

So if you were to abruptly stop those opioids from one day to the next, that patient would have a physical withdrawal and would be sick. But that's not being addicted. That's just a physical dependence that happens to everybody. In fact, it happens to every mammal if you give a significant dose over a significant time.

Similarly, the tolerance is that if you give a significant dose over a significant time, the medication will have less effect. The patient will become tolerant. And, again, that's a normal physiologic thing that will happen to everybody with a sufficient dose over a sufficient time, whereas addiction is something that's a psychological phenomenon, compulsive use cravings, that does not happen to everybody. It happens to a relatively small percentage of patients. When it does happen, it can be absolutely devastating, so as to not confuse the patient developing physical dependence or physical tolerance with a patient developing addiction.

Q. And I'd like to go to the next stop on the timeline.

Before I do, we've been focusing on some seminal publications relevant to the standard of care question.

Do you have an understanding as to whether there was a much broader discussion occurring regarding standard of care that these are leading examples of?

A. These are examples of the evolution of that standard of care, but they reflect a broad discussion across pain medicine, and actually medicine in general, about what's the appropriate way for us to treat pain and what's the appropriate way for us to use opioid pain medications to treat pain.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. I've passed you a document AM-WV-2693. It says "Joint Commission on Accreditation of Healthcare Organizations Pain Standards for 2001." Are you familiar with this document?

A. Yes, I am.

Q. Are you familiar with the entity that issued this document, the Joint Commission on Accreditation of Healthcare Organizations?

A. Yes, I am. We, we call it by the acronym JCAHO.

Q. And what role, if any, do they play in the medical profession?

A. So JCAHO is the body that accredits hospitals and they accredit other healthcare organizations. And that accreditation is very important to us to continue to be able to operate our hospitals. An accredited hospital has implications for reimbursement, et cetera. So their accreditation is extremely important to us.

Q. And these are, are pain standards for 2001. What, if anything, is the significance of this accreditation on issuing pain standards, or any kind of standards for that matter?

A. So the significance of any standards that JCAHO issues is that they come and inspect us on a regular basis. Often it's a surprise inspection that you don't know of ahead of time where they arrive. And they inspect whether we're meeting their standards for pain treatment or for keeping the operating rooms sterile, clean enough, or many other things.

And it's very, very important to us to maintain our accreditation, and very important for us not to have findings where we're not meeting their standards beyond how we treat pain or other things.

Q. Okay. In terms of these specific pain standards, do you know whether they are influential in the practice of medicine?

A. Yes, I do.

Q. How so -- or how were they if at all?

A. So they were influential because they set standards for measuring pain as the fifth vital sign --

Q. Uh-huh.

A. -- which was extremely important because if you think of vital signs, the name, the name says a lot; heart rate, blood pressure, et cetera, key things. And to then add pain as a fifth vital sign was a very clear message of how important JCAHO felt measuring pain and, by implication, treating pain was and so, therefore, the expectation that hospitals who are going to be inspected by JCAHO would, would meet those sort of standards.

Q. I'd like to look at what exactly this document says on that.

MR. SCHMIDT: Before I do, we move this document into evidence for the limited purpose of notice, AM-WV-2693.

MR. ACKERMAN: One thing, Your Honor -- we tried to point this out last night in our objections. It appears that the back there's a different document that's appended to it. So you've got ten pages that all appear to be the same document, and then there's something else.

THE COURT: Beginning on page --

MR. ACKERMAN: Page 11 at the bottom it looks like something that is Page 13 of a separate document.

MR. SCHMIDT: I think the cover of the document

answers that in the second paragraph. It refers to the new pain standards and some examples are pulled out of the six chapters in which they appear in these six manuals and are shown below for your information.

So it's, it's an attachment to the original document that's referenced in the second paragraph on the first page.

THE COURT: Yeah. The paragraph on the first page appears to embrace the parts that you're concerned about, does it not?

MR. ACKERMAN: I think when it says examples are shown below, it's talking about the content of the document.

MR. SCHMIDT: This document has been on the exhibit list for a long, long time. It's one of the central documents in the case. I actually moved it into evidence as an adoptive admission because it's subject to a --

THE COURT: I'm going to admit it for the limited purpose, Mr. Ackerman. You can object -- do you want the record to show your objection?

MR. ACKERMAN: I think it's on the record, Your Honor.

THE COURT: All right. It will do so.

BY MR. SCHMIDT:

Q. Let's go to Page 12 of this document if we could. It's the number in the middle this time at the bottom. And it says "Standard" at the top.

And, actually, just before I do, just to make the record complete, Dr. Gilligan, could you look back with me at the first page of the document.

The second paragraph says, "The new pain standards and some examples are pulled out of the six chapters in which they appear in these six manuals and are shown below for your information."

Do you see that?

A. I do.

Q. Let's go to Page 11. Remembering those, those words from the first page about standards and manuals -- I'm sorry, Page 12, please.

You see at the top there's a reference to a manual, the Comprehensive Accreditation Manual for Hospitals: The Official Handbook. Do you see that?

A. I do.

Q. And then below that there's a reference to "Standard." Do you see that?

A. I do.

Q. The standard is patients have the right to appropriate assessment and management of pain. Do you see that?

A. I do.

Q. And then it looks like the way this document works is it explains that standard. And it says, "Pain can be a common part of the patient experience. Unrelieved pain has

adverse physical and psychological effects. The patient's right to pain management is respected and supported. The healthcare organization plans, supports, and coordinates activities and resources to assure the pain of all patients is recognized and addressed appropriately."

Do you see that?

A. I do.

Q. And what, if anything, is the import of this being part of an accreditation manual and standard set of that manual in JCAHO?

A. So it's of substantial import again because we are accredited by JCAHO and because it's very, very important to us to maintain our accreditation, and very important for our accreditation inspections not to have findings where we're deficient. So in a set of standards like this, that has a big effect on, on us running the hospital.

Q. Let's go back to the page we were looking at, please, if you could pull that back up, 2693, AM-WV-2693, Page 12.

And while we're pulling that up, we can look at our hard copy documents just in the interest of time.

Do you see there's a heading below the standard below the explanation of the intent of the standard that says "examples of implementation"? Do you see that?

A. I do.

Q. And do you see the references, what you were telling us

earlier, it says, "Pain is considered a fifth vital sign in the hospital's care of patients. Pain intensity ratings are recorded during the admission assessment along with temperature, pulse, respiration and blood pressure."

Do you see that?

A. I do.

Q. And was that a significant consideration in the standard of care in medicine at this time?

A. That was a significant consideration again because the, the other vital signs have been around for -- temperature, pulse, respiration, blood pressure have been vital signs that are critical to assessing patients.

And, so, to add pain as a fifth vital sign was a very clear message about the great importance of measuring pain and, by implication, of treating pain.

Q. Okay. And you see that as, as Item Number 1 under examples. And let's just go to the board and put that up on the board.

We're now to 2001. Pain is considered the fifth vital sign.

Can we go back to the second example, AM-WV-2693. "Every patient is asked a screening question regarding pain on admission."

And then let's just jump down to Number 4. "The following statement on pain management is posted in all

patient care areas (patient rooms, clinic rooms, waiting rooms, et cetera). Statement on pain management: All patients have a right to pain relief."

Could you comment on the impact of some of these examples that were given on how to implement this policy in terms of every patient being asked a screening question about pain, public postings that we've probably all seen, all patients have a right to pain relief.

A. So where every patient is asked a screening question about pain on admission, then you're getting a measurement of pain by JCAHO guidance on every patient. And that's extremely likely to have an effect that you'll now be doing more to treat patients' pain.

If the measurement is very high, the likelihood that doctors and nurses will then do something to try to treat it is, I think, a borne out conclusion. And also having the statement posted in all patient care areas per JCAHO recommendations, per JCAHO standard setting saying all patients have a right to pain relief is, is a very clear statement that if a patient has severe pain, there's a strong implication that doctors and nurses should, in the appropriate fashion one would hope, treat, treat their pain.

Q. Let's go to the next item on the timeline.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. I've given you MC-WV-1522 which is titled "A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration."

And then if you look on the right, it appears that it lists the different organizations. Do you see that?

A. I do.

Q. And one of them is -- the sixth one down is the American Medical Association. Do you see that?

A. I do.

Q. What is the import, if anything, of receiving a statement from the American Medical Association?

A. The American Medical Association is the biggest organization representing doctors in America. So it's significant when they're endorsing a statement.

Q. If you scroll down, this was in the title, but do you see the reference to the Drug Enforcement Administration being listed?

A. I do.

Q. And it's on the right there, yeah. And then if we go back to what this joint statement addresses, it states, "Promoting pain relief and preventing abuse of pain medications, a critical balancing act."

Do you see that?

A. I do.

Q. Is there -- what significance, if any, does a statement from the DEA on balancing pain relief and preventing abuse to pain medications carry?

A. So it's significant because the Drug Enforcement Agency, of course, part of what they're, what they will do is look at inappropriate use of medications and be an enforcement agency.

So when they're endorsing promoting pain relief while getting the -- while preventing abuse, that's significant because the doctor who would be -- might be scared to prescribe opioids for fear of getting in trouble with enforcement agencies would take -- would tend to take quite seriously a message from the Drug Enforcement Agency endorsing these medications to treat pain in many situations.

MR. SCHMIDT: I'll move into evidence MC-WV-1522 for the limited purpose of notice.

THE COURT: Any objection?

MR. ACKERMAN: For the limited purpose, no objection.

THE COURT: Let me make clear it's notice to, to whom for what?

MR. SCHMIDT: Notice to the medical and healthcare community regarding the contents --

THE COURT: Regarding the changing standards of

the abuse of opioids?

MR. SCHMIDT: Yes, Your Honor.

MR. FARRELL: I've got an objection to that. I think it's notice to the defendants, not notice to -- there's no relevance to the notice to the community.

MR. SCHMIDT: It's a publication from, among other sources, the American Medical Association and the branch of the federal government that regulates all doctors who prescribe prescription opioids. We're talking about standard of care. I think it is relevant to notice to doctors.

THE COURT: I think it is too, Mr. Farrell. It shows the -- it doesn't come in for the truth of the matter asserted. It comes in to show notice to the medical profession of the changing standards of the use of opioids. Isn't that the purpose it's offered, Mr. Schmidt?

MR. SCHMIDT: Yes. I think we actually could move it in as a public record.

MR. FARRELL: Okay.

THE COURT: I'll admit it for the limited purpose. Do you want to object, Mr. Farrell?

MR. FARRELL: No. I guess I'm just a little confused, but that's okay.

BY MR. SCHMIDT:

Q. So let's look at what this statement says. If we

look -- there's a line, looks like the third paragraph down, "This consensus statement is necessary based on the following facts." And then it lists a series of facts. I'm going to focus on the first two. Do you see that?

A. I do.

Q. The first fact, according to this document, that necessitates this consensus statement is that, quote, "Under-treatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important part of the quality of medical care and pain should be treated aggressively."

Do you see that language?

A. Yes, I do.

Q. Again, does this reflect the standard of care this time from the entire American Medical Association and the DEA about the needs, in the words of this document, to not simply recognize the problem with under-treatment of pain, but that pain should be treated aggressively?

A. Yes, this is part of that changing standard of care.

Q. Let's look at the next bullet. It says, "For many patients opioid analgesics, when used as recommended by established pain management guidelines --" do you see that

language?

A. I do.

Q. And what do you understand that reference to mean, established pain management guidelines?

A. Things like the guidance from the Federation of State Medical Boards and other similar guidelines.

Q. "For many patients, opioid analgesics, when used as recommended, are the most effective way to treat their pain and often the only treatment option that provides significant relief." And did I read that correctly?

A. Yes, you did.

Q. If we switch over to our board and put that on the board, is that significant when the DEA and the AMA are coming out with a statement saying that it's important to treat pain and they're often the only treatment option that provides significant relief?

A. Yes, it's important, again the AMA being the biggest organization representing doctors in the U.S. and the DEA being the Drug Enforcement Agency.

Q. Okay. Can we go back to the original document, please, MC-WV-1522. And do you still have that in front of you?

I think we're having some technical problems. While we're doing that, I'm going to ask you about one other paragraph in here. It's the third paragraph in the document right before that discussion of the consensus statement

being necessary based on the following facts.

Do you see where it says, "Preventing drug abuse is an important societal goal but there's consensus by law enforcement agencies, healthcare practitioners, and patient advocates alike that that concern should not hinder a patient's ability to receive the care they need and deserve."

Do you see that language?

A. I do.

Q. Do you have an understanding that there was that consensus described here at this point in time by law enforcement, by healthcare practitioners, by patient advocates that concerns about abuse were important, but they shouldn't hinder a patient's ability to receive the care they need?

A. Yes. My understanding is that that was the consensus view at that time.

Q. The FSMB continued to issue guidelines over time?

A. Yes, they did.

Q. Let's take a look at the next set of guidelines, if I may just have one second, Your Honor.

THE COURT: Yes.

MR. SCHMIDT: May I approach?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. I've handed you what I've marked as Defense West Virginia 3605. And let's put it up on the screen just in terms of what we're looking at. It says "Model Policy for the Use of Controlled Substances, Federation of State Medical Boards." And then there's a reference to May, 2004. Do you see that?

A. I do.

Q. Is this an update on those Federation of State Medical Board standards now from 2004?

A. That's correct.

MR. SCHMIDT: We'd move this into evidence for the limited purpose of notice as described before, Your Honor.

THE COURT: Any objection?

(No Response)

THE COURT: Hearing none, it's admitted.

BY MR. SCHMIDT:

Q. If we look in the second paragraph, it states, "Since adoption in April 1998 --"

Is that a reference to the earlier guidelines we looked at?

A. Yes, it is.

Q. "-- the model guidelines for the use of controlled substances for the treatment of pain have been widely distributed to state medical boards, medical professional organizations, other healthcare regulatory boards, patient

advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other healthcare providers. The model guidelines have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities."

Do you have that understanding that their model guidelines were endorsed by various organizations, including the DEA?

A. Yes, that is my understanding.

Q. Let's go to the next paragraph, please.

It states, "Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be under-treated."

Do you see that?

A. I do.

Q. So just to orient us, we're now in 2004. Are you aware that prescription levels had actually started increasing by this point in time?

A. Yes, I am aware they had.

Q. Was the Federation of State Medical Boards telling doctors they could still do more to treat acute and chronic

pain?

A. Yes, I think that's a fair statement of what they're, of what they're saying.

Q. Let's go to Page 3. Actually, let's just put that statement, if we could, up on the board.

We're now to 2004. Recognizing that they continued -- let's go back to Defense West Virginia 3605 at the bottom of Page 2, last sentence, or second to last sentence.

It says, "Appropriate pain management is the treating physician's responsibility. As such, the board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis."

What's the import of the Federation of State Medical Boards proposing that the medical standard will involve the board considering inappropriate treatment of pain to be a departure from standards of practice and will investigate?

A. So what the Federation of State Medical Boards is telling doctors there is that if you do not adequately treat patients' pain, you will have failed to meet the standards of care, or standard of practice care they use.

And, again, where medical boards are the bodies that grant you your license and can take your license away, a

recommendation of that sort from the Federation of State Medical Boards has a significant influence on doctors.

Q. Next sentence repeats or says something similar.

Can you cull that out, the next sentence on Page 3?

"The board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins."

Is that a similar statement about the role of prescription opioids that we saw in the earlier document?

A. Yes, it's very similar. And, again, it specifically calls out chronic non-cancer origin in addition to acute pain and cancer pain.

Q. Okay. Let's go to the next document on our timeline. I want to just illustrate whether this tracked through into West Virginia standards with a document in evidence.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes. I don't think you moved 3065 into evidence. Do you want to do that?

MR. SCHMIDT: Yes, I would for the limited purpose of notice, Your Honor.

THE COURT: All right. Is there any objection?

MR. ACKERMAN: Not for the limited purpose.

THE COURT: All right. It's admitted for the limited purpose.

MR. SCHMIDT: Thank you, Your Honor.

BY MR. SCHMIDT:

Q. So if we put MC-WV-1218 up on the screen, do you see that this is a West Virginia Board of Medicine quarterly newsletter from January, 2005?

A. I do.

Q. And just two quick points on this.

If we can scroll down, please, to the first paragraph.

Remember in that earlier document there was a reference to the inappropriate treatment of pain?

A. I do.

Q. Do you see that defined here in this last sentence for the purposes of this policy, the inappropriate treatment of pain includes non-treatment, under-treatment, over-treatment, and the continued use of ineffective treatments?

A. I, I see that.

Q. And then I just want to look down at the bottom of this page. Do you remember me reading you that language from the FSMB document about the board will consider the inappropriate treatment of pain to be a departure from standards?

A. I do.

Q. Do you see that same language here adopted by the State of West Virginia, "The board will consider the inappropriate

treatment of pain to be a departure from standards of practice and will investigate such allegations."

Is that guided by the Federation of State Medical Boards?

A. That would be my understanding because it's verbatim from what we saw in the FSMB.

Q. And if we go to the next page, please, do you see a similar statement from the West Virginia Board of Medicine right at the top recognizing that opioids may be essential in the treatment of acute pain due to trauma or surgery and chronic pain whether due to cancer or non-cancer?

A. I see that.

Q. And let's, let's put that up on the board if we could.

The Court has heard evidence about a book by a Dr. Fishman and I'm not going to -- it's in evidence. The Court has a copy. I'm not going to spend a lot of time on it. It was actually mailed to every doctor in West Virginia called "Responsible Opioid Prescribing." Are you familiar with that Dr. Fishman book?

A. Yes, I'm familiar with the book.

Q. And if we -- let's put up on the screen MC-WV-2111 and go to Page 15 of the document.

I want to just highlight some language the Court has seen.

"Patients should not be denied opioid medications

except in light of clear evidence that such medications are harmful to the patient."

Do you see that?

A. I do.

MR. SCHMIDT: Mr. Reynolds, can you put that up on our board?

BY MR. SCHMIDT:

Q. We're now to 2008 and the corresponding transmission of this to all doctors in West Virginia.

MR. SCHMIDT: And if we go back to the book itself and cull out that first bullet that was on Page 15. Then can you also cull out the third bullet. Is it possible to get both of them together?

BY MR. SCHMIDT:

Q. I read you the first one. The third one says, "Physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances."

Do you see that?

A. I do.

Q. Do you understand this book that was sent to every West Virginia doctor to be in line with standard of care at this time in terms of when opioids should be prescribed and having a responsibility to minimize the potential for abuse and diversion?

A. Yes. I think it was a clear message that on the one hand doctors should appropriately use opioids to treat patients' pain, but that also doctors have a responsibility to think beyond just the patient in front of them to think about the potential for abuse and diversion of those medications.

Q. Okay. How do you mesh those two statements?

A. I mesh those two in terms of the same sort of balancing that I think is characteristic in many areas of the practice of medicine, and certainly in this area of prescribing opioid medications that you're talking about, you're talking about significant potential benefits, but you're also talking about significant potential risks, and that the doctor is -- as part of his or her job is supposed to think through those, that risk benefit and weigh it as appropriately as he or she can with the information available to them.

Q. Two more documents on this timeline if I could.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes.

BY MR. SCHMIDT:

Q. And I'll try to do these as quickly as possible.

The first document is Defense West Virginia 1944 which is not in evidence. The second document is Defense West Virginia 1935 which is in evidence.

My question to you is simply if you -- Defense West Virginia 1944 is dated --

MR. ACKERMAN: Your Honor, --

MR. SCHMIDT: -- 2005.

MR. ACKERMAN: We have an objection to the use of Defense West Virginia 1944 because the document did not appear on the expert's materials considered list.

MR. SCHMIDT: It does not. That is correct. It's substantively identical in terms of what I'm asking him about to the later version of the document that does.

MR. ACKERMAN: Your Honor, I think we went through this with some of our experts that materials that weren't in the report you're not allowed to ask about.

THE COURT: Well, I'll sustain the objection. You can use it as a basis to ask him a question if you want to, Mr. Schmidt.

BY MR. SCHMIDT:

Q. Okay. Let's start with Defense West Virginia 1935, Page 2. Do you recognize this is from September 9th, 2013, from the State of West Virginia policy on the use of opioid analgesics?

A. I do.

Q. If you look a little further up, do you see that in this one they're actually clear that they took it from these Federation of State Medical Board documents we've been

talking about?

A. I see that.

Q. And in the interest of time, I will go to the third page of this document. And do you see in the third paragraph, the first sentence references again the statement about opioid analgesics are useful and can be essential in the various range of pain treatments that we've talked about, acute pain, chronic pain, whether due to cancer or non-cancer causes?

A. I see that.

Q. And if we go to the two paragraphs down, patients (verbatim) should not fear disciplinary action from the board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose in the course of professional practice when current best clinical practices are met.

Do you see that?

A. I do.

Q. And then if we look at the next sentence, they define when use of opioids is for a legitimate medical purpose. And they say if it's based on sound clinical judgment and current best clinical practices, is appropriately documented and is of demonstrable benefit to the patient. Do you see that?

A. I do.

Q. What's the import of a State Board of Medicine telling doctors in that state, statements like this about appropriate use of, of prescription opioids?

A. The importance of it is that the State Medical Board is giving physicians here a fairly clear message that they would not be -- they shouldn't fear disciplinary action by the board as long as they practice meeting the standards of appropriate care. And, so, that they shouldn't let that fear of potential discipline stop them from using opioid pain medications in an appropriate fashion.

Q. Do you see similar statements -- let's go to the board. Let's put up the two documents we just used, Defense West Virginia 1944 from 2010 and Defense West Virginia 1935 from 2013 on the board. Do you see similar statements in between 2005 and 2013?

A. I did.

Q. Okay.

MR. SCHMIDT: Your Honor, may I pass up a copy of this for demonstrative purposes? Plaintiffs' counsel already has it.

THE COURT: Yes.

MR. ACKERMAN: Of what?

MR. SCHMIDT: Of the completed time line.

MR. ACKERMAN: Oh, okay.

MR. SCHMIDT: Thank you.

Your Honor, I briefly conferred with Mr. Farrell. I have about 10 minutes left. I was hoping to be done. Mr. Farrell was very gracious to say if I'm not done by noon that that gives him enough time. This might be -- if that's okay with the Court, this might be a good time to break.

THE COURT: Yeah, let's go ahead and finish the direct and then we'll take the lunch break and come back and you can cross him after lunch.

MR. FARRELL: I think Mr. Schmidt was asking whether or not he could take 10 minutes after the break to finish up and that way --

THE COURT: Is that what you were asking?

MR. SCHMIDT: Yes, but I'm good either way, Your Honor.

THE COURT: Well, I'm going to suggest we come back at 1:30. Is that okay with everybody?

MS. MAINIGI: Yes, Your Honor.

THE COURT: We'll be in recess until then.

(Recess taken at 12:01 p.m.)

(Proceedings resumed at 1:27 p.m. as follows:)

THE COURT: Okay, Mr. Majestro.

MR. MAJESTRO: Your Honor, you asked me yesterday how much time we needed to respond to the motions and I wisely waited to see them before I committed myself.

Following court yesterday, the defendants began filing

motions, ended over the noon hour. They filed five motions totaling 214 pages of text, none of them within the Court's page limits.

I understand these are important issues, but I would point out two things about the issues.

A lot of what's here is either, is either an attempt to re-litigate issues in a -- with different theories or arguments that have never been raised before in this litigation.

Mr. Heard yesterday talked about, "After four years I still haven't seen a case," or such and such. Well, this is -- the first time he raised that argument was yesterday.

And, so, we've had U.S. Supreme Court precedent going back to historical roots of equity jurisdiction. It's complicated.

In addition, you know, our team -- we're allocating resources among the lawyers working on these cases across the country. Our teams have split up. We have people currently working on the, on the State Court cases in California, in New York, and also getting ready for the -- Judge Polster's trial. They're getting ready to -- getting the dispositive motions and *Daubert* deadlines for those trials.

And as I mentioned to your law clerk before the hearing, I also have a personal event next week that's going

to have me out-of-pocket for a few days.

With all that, we're not going to file a motion to strike these motions for violation of the page limits. And I, I admit that we have been a little lax in those. But it's always been done by consent and never to the extent that this has happened.

But you asked me how much time I needed to do the right kind of job and it's a month.

THE COURT: Ms. Mainigi.

MS. MAINIGI: Your Honor, I think a month is, is just way too long for these motions. I mean, they're clearly timely motions and we know that we filed a lot of papers. I think our papers are exactly on point and consistent with what we needed to file for directed verdict motions.

And, so, with respect to -- there's a couple of points.

Number one, they have seven law firms that are working on this matter. So there are -- I certainly don't begrudge Mr. Majestro taking time off for his daughter's wedding. Absolutely he should be doing that. But I think that there -- just like we've had to divide up our resources across the country in various jurisdictions, they have done the same thing and this is a trial. We're in the midst of trial and we're moving.

THE COURT: Have the defendants filed everything

they intend to file with regard to the 52(c) motions?

MS. MAINIGI: Yes, Your Honor, to my knowledge. I'm not aware of --

THE COURT: So you're done?

MS. MAINIGI: We're, we're done, Your Honor.

And one key important fact that I'd like to share with the Court, which I hope will make everybody's Friday afternoon, we've been taking a close look at our case and we've been taking a look at the types of, the pieces of evidence that we were able to get in during discovery, especially since many of our corporate witnesses were called in the plaintiffs' case. And, and we think that we're looking on the outside at three more weeks of trial.

So, obviously, some of that is dependent on how long the cross-examinations will be. And, certainly, I don't want to delay Dr. Gilligan by slowing this down on the schedule. We're certainly happy to discuss that with you all whenever you're ready. But when we're looking at on the outside three weeks of trial, I do think a month ultimately for briefing and directed verdict is just not feasible.

And so our suggestion, Your Honor, is that the proximate cause motion, for example, could be filed within a week, and then everything else within two weeks. And I do think that the plaintiffs have the resources to get that done.

There is many a time where we have made filings overnight and utilized all of our resources, even those folks not in trial, to get that work done at the end of the day.

So we think that would be quite reasonable under the circumstances, one week for proximate cause and then two weeks for the balance given that we're looking on the outside at three weeks.

THE COURT: Mr. Majestro, how much time do you need to take off for your daughter's wedding? I want you to go and have a good time.

MR. MAJESTRO: I, I was planning on being gone Thursday, Friday. I'm putting on one witness next week also.

The other point I'd make, Your Honor, is that the -- then I planned to be not working the entire weekend.

You know, Rule 52(c) -- this sounds to me like if these issues are that complicated that they needed to file two hundred and some pages of briefs that maybe this is another ground for exercising your jurisdiction and deferring ruling on these.

If they're going to be done in three weeks, that, that seems to me -- I mean, I -- even under their schedule I assume they're going to be filing a reply. And, so, it seems to me we're going to be at the end of trial anyway.

And, so, taking the time to do the motions right -- and I'm especially -- you know, the, the proximate cause motion is not just one motion because all of the three, all of the three defendants touched on proximate cause individually in addition to the global motion.

And the 71-page brief that Ms. Mainigi just filed is, is a very complicated one. It is something that's going to -- and raises completely new issues in the litigation undoing further rulings that Your Honor has already made or attempting to. And, you know, I think it's a real motion. I'd like the time to do the research and get that stuff right.

MS. MAINIGI: Your Honor, we do think -- these are very serious motions, as Your Honor recognized from the arguments yesterday, and they definitely deserve the attention of this Court when the Court has the opportunity.

THE COURT: And having said that, that deserves Mr. Majestro time to produce the kind of work product that the defendants have produced which is -- all that will be very helpful to me.

And I'm going to give you three weeks, Mr. Majestro.

MR. MAJESTRO: I think we can make that work. I appreciate it, Your Honor.

THE COURT: Three weeks from, three weeks from --

MR. MAJESTRO: Today.

THE COURT: Three weeks from today. And we're going to finish the evidence if we stick to the original schedule and take a couple weeks off and then come back for final arguments. But this briefing, I would think, will certainly facilitate the consideration of the issues that will be argued in the final arguments if we get that far.

MS. MAINIGI: Your Honor, with respect to that -- again, we can discuss this later this afternoon or when we return. The defendants would, depending on the timing, would really like to fit in final arguments in July if that is possible.

And the reason for that, candidly, is various of us -- many of us will have to move onward to trial in September in Washington state, and we'd like to spend August with our families and take vacation and all of that. And, so, we will certainly work consistent with Your Honor's schedule.

THE COURT: Well, let's see where we get. And finishing by the end of July would certainly be welcomed by the Court.

MS. MAINIGI: I think it would be welcomed by everybody in this courtroom, Your Honor. But we, we can address that later. And we can even propose a schedule to the Court and the plaintiffs, if that makes sense to, to you.

And it looks like we've decided a date. We would just

ask if the plaintiffs are able to get the briefs done on a rolling basis, I think that would certainly help everybody to have that happen within the three-week period.

MR. MAJESTRO: I mean, to the extent that's possible. I, I anticipate filing -- I'm going to -- some of them are overlapping in the sense that they're the same argument with different factual bases. So some of them are going to be -- one response will go to multiple motions.

So to the extent we can do that, I'm happy to. But I can't make any promises here until we've gotten further into it.

THE COURT: Okay. Well, you've got three weeks, Mr. Majestro.

MR. MAJESTRO: Thank you, Your Honor.

THE COURT: And I look forward to your work product. And we need to get Dr. Gilligan on and off.

MR. SCHMIDT: Your Honor, just -- just as a matter of housekeeping, Your Honor, before the break we had submitted the timeline that we spent building with Dr. Gilligan as a court exhibit. I just put a sticker on it for official purposes, if I may submit it as McKesson Demonstrative 11.

THE COURT: All right.

You may resume the stand, Dr. Gilligan.

BY MR. SCHMIDT:

Q. Good afternoon, Dr. Gilligan. I'll pick up where we left off. We walked through --

MR. SCHMIDT: And, and could we just put up the timeline just to orient us very quickly, McKesson Demonstrative 11, if that's possible?

BY MR. SCHMIDT:

Q. So we walked through these various statements from the national groups, West Virginia Board of Medicine, took us up until 2013 with the West Virginia Board of Medicine, repeated a statement about prescription opioids being essential in certain instances in the treatment of acute pain and certain types of chronic pain.

Since that time, has the standard of care for prescription opioids continued to evolve?

A. Yes, it has.

Q. And, and how has that impacted prescribing rates in the time period since we were walking through?

A. So in the time period since what we walked through, it has gotten more conservative.

Q. Uh-huh.

A. And accompanying that, prescribing rates have gone down.

Q. From your perspective, has that been driven by the medical profession?

A. Yes.

Q. And if you could characterize the state of prescribing today, how would you characterize that in terms of prescription opioids?

A. So it's significantly more conservative than the mind-set in many of the years, or in the years shown there, certainly many of the years shown there, with more awareness of the potential ill effects, adverse effects from medications, risks of the medications for patients, a greater weighting on that, and also with more skepticism about the benefits.

Again, you know, some patients do well, but a rise in awareness that many patients won't benefit from them so, therefore, a shifting of the risk benefit.

Q. Okay. Mindful of what you just said, are prescription opioids still prescribed today for acute pain, just more narrower perhaps?

A. Yes, they are.

Q. Are they still prescribed for cancer pain?

A. Yes, they are.

Q. And, again, mindful of what you told us about the science on non-cancer chronic pain and what you said just now, are they still prescribed in certain instances for non-cancer chronic pain?

A. Yes.

Q. I'd like to show you a document on some of these points we've been talking about just now in terms of current standards.

MR. SCHMIDT: May I approach, Your Honor?

THE COURT: Yes, you may.

BY MR. SCHMIDT:

Q. And just to orient us as to what we're looking at, this is Defense West Virginia 2527. If we look at the top of the document, we see the AMA logo, the date June 16th, 2020. And it looks like it's written to the Chief Medical Officer of the U.S. Centers for Disease Control and Prevention. Do you see that?

A. Yes, I do.

Q. Are you familiar with this letter from the AMA?

A. Yes, I am.

MR. SCHMIDT: Your Honor, we move this into evidence for the limited purpose of notice.

THE COURT: Any objection?

MR. FARRELL: Yes, Your Honor. I'm not quite sure how an expert witness is able to lay the foundation for a document written by somebody else and sent to a third party about a subject matter that he was not involved in with the drafting or writing of this letter. Sure, he can testify to it all he wants, but this isn't a vehicle to be entering into the record.

THE COURT: Can you lay a little better foundation, Mr. Schmidt?

MR. SCHMIDT: Yeah, yeah, I'll do my best.

BY MR. SCHMIDT:

Q. First of all, do you understand this to be a private letter that we somehow obtained or a public letter?

A. I understand it to be a public letter.

Q. Do you understand this document to be publicly available to members of the medical profession?

A. Yes, I do.

Q. And in terms of -- if we look at the first sentence of this document, it says it's on behalf of the American Medical Association and our physicians and medical student members. Do you see that?

A. I do.

Q. When the AMA is writing on behalf of themselves and their physician medical student members, who is that?

A. Well, the AMA, as we discussed, is the biggest association of doctors in the U.S.

Q. And after they say that they're writing on behalf of themselves and the physicians and medical student members, they say the AMA appreciates the opportunity to --

MR. FARRELL: Objection, Your Honor. I didn't make my first objection just to provide the opportunity to

read it into the record.

MR. SCHMIDT: I'm trying to lay the foundation as to what the document is and why --

THE COURT: I'm satisfied with the foundation he's laid so far.

Mr. Ackerman.

MR. ACKERMAN: Yeah. I am curious as to Mr. -- or counsel offered the document for purposes of notice. My question is notice of what to whom?

MR. SCHMIDT: Notice of the consensus in the medical profession to doctors who are being spoken for on -- in this letter and to the healthcare system.

THE COURT: I'm going to admit it for the limited purpose. We need to get through Dr. Gilligan here.

MR. SCHMIDT: Okay.

THE COURT: Go ahead, Mr. Schmidt.

MR. SCHMIDT: Thank you, Your Honor.

BY MR. SCHMIDT:

Q. I'll jump past -- well, actually, just to finish this sentence, do you see that there's reference -- they're saying they appreciate the opportunity to review and comment on the Centers for Disease Control and Prevention guidelines for prescribing opioids for chronic pain originally published in 2016.

A. I see that.

Q. Do you remember this morning you and I touched on those CDC guidelines?

A. Yes, I do.

Q. Could you just remind us of the effect of those CDC guidelines?

A. So the CDC guidelines laid out numerous steps recommending essentially that doctors should be more conservative, more cautious in their prescribing of chronic opioid therapy for non-cancer pain.

Q. Okay. Go to Page 3 of the document, please, down at the bottom. Do you see there's reference to AMA Task Forces?

A. Yes, I do.

Q. "The Task Forces further affirm that some patients with acute or chronic pain can benefit from taking prescription opioid analgesics at doses that may be greater than guidelines or thresholds put forward by federal agencies." And then it lists other bodies. Do you see that?

A. I do.

MR. FARRELL: Objection, Your Honor. Again, this is a letter by a third party written to another third party that's being read into the record by a fourth party. If Dr. Gilligan wants to testify what he believes to be the standard of care, we have no objection. He's well qualified. But neither Deborah Dowell nor James Madara have

been called into this courtroom.

THE COURT: Mr. Ackerman.

MR. ACKERMAN: Yeah. I would add that I don't think reading this, this sentence is consistent with admitting the document for a limited purpose. If it's a limited purpose of notice, that's fine, but --

THE COURT: Well, I'll sustain the objection. But you can ask him the questions without reference to the document, Mr. Schmidt.

BY MR. SCHMIDT:

Q. Do you, do you --

MR. SCHMIDT: Where I was going, Your Honor --

THE COURT: If I understand it.

MR. SCHMIDT: Yeah. What I was going to ask him was does he understand this to be the standard of care.

BY MR. SCHMIDT:

Q. So do you understand the standard of care in the medical profession to reflect that patients with acute or chronic pain, some patients can benefit from taking prescription opioids at doses that may still be greater than guidelines or thresholds set by the Federal Government or other agencies?

A. Yes, I do understand that to be the consensus within the standard of care.

Q. And last question about this document. If we go to the

first page, in the last paragraph on the first page there's language about the nation no longer having a prescription opioid-driven epidemic. What we're now facing is a different --

MR. ACKERMAN: Objection.

THE COURT: You're doing the same thing that I sustained the objection to.

BY MR. SCHMIDT:

Q. Do you have an understanding, sir, as to whether --

MR. ACKERMAN: I'd ask that the portion that we just objected to be taken off the screen.

MR. SCHMIDT: It's off the screen.

BY MR. SCHMIDT:

Q. Do you have an understanding as to whether the nature of, of drug abuse involving opioid products has shifted from prescription drugs to illegal heroin and fentanyl over the past decade?

A. Yes, I do.

Q. And what, what is that understanding?

A. That it has shifted in that way, that it has shifted from abuse and misuse of prescription opioids to abuse and misuse of heroin and fentanyl and fentanyl analogues that are illicit fentanyl, not, not pharmaceutical fentanyl.

Q. Just a few questions to round out our, our time together.

As a prescribing physician covering the time period we've been talking about, including the increase in prescriptions and then the decrease in prescriptions, do you have an opinion as a prescribing physician as to which healthcare decision-makers in the healthcare process drove those changes in prescribing in both directions?

A. Yes, I do.

Q. What is that?

A. Physicians and other prescribing clinicians.

Q. And from your experience, when we were at the peak or moving up to the peak or coming back down, do you have an understanding as to whether that prescribing was driven by good faith medical decisions?

A. Yes. I think the great majority of the over-prescribing was well-intentioned. The majority of opioid prescribing during much of that period, or perhaps all of that period was by primary care physicians.

And, so, I think there was a great majority of cases of well-intentioned clinicians trying to follow what they understood, or in some cases what they had been told, was the right way to treat patients.

Q. Do you have a view as to whether distributors drove prescribing decisions by doctors in terms of their understanding of risks and benefits?

A. I do.

Q. What's that opinion?

A. I don't think distributors had an influence on doctors' prescribing decisions.

Q. As someone who's had occasion to prescribe medication and prescription opioids throughout your career, have you ever done so based on interactions with a pharmaceutical distributor?

A. No, I have not.

Q. In your experience, do distributors -- your experience in the real world dealing with other doctors, do distributors play a role that's meaningful in determining how many prescriptions for opioids or any other product get written in a given point in time?

A. No, they do not.

Q. That's all I have, Dr. Gilligan. Thank you.

THE COURT: All right. You may cross-examine.

CROSS EXAMINATION

BY MR. FARRELL:

Q. Good afternoon. I introduced myself earlier. I'm Paul Farrell on behalf of the County Commission and City of Huntington plaintiffs in this case.

I want to take this opportunity to use your expertise to maybe crystalize or clarify some of the concepts that we've talked about over the past several weeks.

We've inartfully used a phrase of a gateway effect. Is

that terminology something that you're familiar with?

A. Yes, it is.

Q. So -- and I'm very confident that you're familiar with the idea and the medical side of it. But from a layman's standpoint or a lawyer's standpoint, gateway effect is intended to communicate that one thing transitions to another.

What is your understanding of the meaning of gateway effect?

MR. SCHMIDT: And I'll just object to the preamble statement.

THE COURT: Overruled.

You understand the question, don't you, Dr. Gilligan?

THE WITNESS: I think I do.

THE COURT: Okay. Go ahead.

THE WITNESS: So I think the gateway effect is when somebody in the context of substance abuse, when somebody goes from one substance to another substance.

BY MR. FARRELL:

Q. So we've had testimony about a lot of articles and I want to ask you a couple of them by name just to see if you recognize them. It's not a test. But Muhury, M-u-h-u-r-y, was addressed earlier. And you're familiar with that?

A. Yes, I am.

Q. And what about Compton, the Compton article in the New England Journal of Medicine? Are you familiar with that?

A. I believe I am, yes.

Q. And then most recently there's been another article by McCabe, M-c-C-a-b-e. Are you familiar with that article?

A. I'd have to see a specific article to know. There might be more than one McCabe article.

Q. This is very true. This is 2021 in the Journal of Addiction Medicine entitled "Pills to powder, a 17-year transition from prescription opioids to heroin among U.S. adolescents followed into adulthood."

I'm not going to -- I'm just asking are you generally familiar with that article?

A. I, I don't remember. I've looked at so many articles, I just don't remember.

Q. Okay. So let me see if I can read some of the concepts and see if we can agree to it.

First of all, you recognize that the Journal of Addiction Medicine is an authoritative text in the field of the treatment of pain?

A. The Journal of Addiction Medicine is a medical journal in the field of addiction medicine. I don't -- I'm not sure when you're saying authoritative text exactly what the definition is there.

Q. That's a legal ease term. Is the Journal of Addiction

Medicine one in which physicians like yourself would rely or use to educate themselves on the state of art of the standard of care?

A. The Journal of Addiction -- it's one of the medical journals that people in my field might read. It's a peer-reviewed journal, yes.

Q. Pardon me. I need my spectacles.

So in this 2020 article it makes reference to Muhury and Compton and it says this. And I'd like to ask you whether or not you agree with it.

"Although the vast majority of prescription opioid exposure does not lead to heroin use, heroin incidence and prevalence rates were significantly greater among those who reported non-medical prescription opioid misuse."

THE COURT: Mr. Schmidt.

MR. SCHMIDT: My objection is just if we're going to read language that's specifically linked to an article, I think it's fair to give the article to the witness.

THE COURT: Well, let's see where we go with this without doing that.

And then if you need to refer to the article, Dr. Gilligan, we'll get you the article.

THE WITNESS: Thank you.

MR. FARRELL: I have to acknowledge, Judge, in my 20 years of doing medical malpractice litigation, this is

the first time my opposing counsel has asked me to share the medical literature, but I have it with me.

THE WITNESS: Thank you.

BY MR. FARRELL:

Q. I'm even going to see if I can put it up on the screen.

Do you see the paragraph -- I'm going to, I'm going to kind of see if I can draw a line on it. This is insane. Now that I want to use it, I can't draw a line on it.

But if you see the paragraph, it says "the percentage of people." Do you see that?

A. I think so. The second paragraph?

Q. Yes. Just to orient you, if you look at the title of the document -- at the top -- the bottom left-hand corner it has the journal reference. You're familiar with the format of these journal articles?

A. Yes, I am.

Q. And what I want to particularly ask you about is the sentence by sentence. I'm going to highlight it right here. And I hope I can tie it all together to make sense at the end. But do you see the sentence I highlighted?

A. More or less I can see it on the, on the screen up front here. I can't see it perfectly, but I think I have a sense of which one you highlighted.

MR. FARRELL: Okay. I wish I had just read it,

Judge. All right. So it's highlighted there.

BY MR. FARRELL:

Q. "Although the vast majority of prescription opioid exposure does not lead to heroin use, heroin incidence and prevalence rates were significantly greater among those who reported non-medical prescription opioid misuse."

And the footnotes, I'll represent to you, are to Muhury and Compton.

Do you agree that's a fair reflection of what Muhury and Compton would say?

A. I think that that's one of the points that was raised in the Muhury article.

Q. And do you agree that that's the state of medical knowledge or an accepted position taken by physicians in your field?

A. I, I think that -- I personally think that that is a fair statement, yes.

Q. All right. So the very next sentence says, "Based on retrospective data --" what is retrospective data?

A. So that's data where you do your study by looking backwards rather than organizing a study that will look -- that you say from here going forward we will collect data and interpret it. Generally, prospective studies are considered a higher grade of science in the majority of

cases than retrospective.

Q. So the reference at the end of this sentence, I'll represent that's Muhury again. And it says, "Based on retrospective data, only one percent of individuals who reported past-year non-medical prescription opioid misuse had used heroin before using prescription opioids."

Do you see that sentence?

A. I do.

Q. And I'm going to try to recapture that in normal words.

Does that basically mean that, that based on this study looking backwards in time that only one percent of the population of heroin users were using heroin before they were abusing prescription opioids?

A. Yes. Only one percent of them had past-year non-medical prescription opioids had used heroin before misusing prescription opioids.

Q. And just from a common sense standpoint, in general people are more likely to abuse opium in the powder form before taking opium with a needle. Is that your experience?

A. I think that people -- some individuals definitely are more likely to use other forms of opioids prior to injecting if they're misusing or abusing them, yes.

Q. And what Muhury is saying is that, that based on this retrospective study, that the number of people that had used heroin first is one percent?

A. That in their study the number of people who used heroin prior to non-medical use of prescription opioids was one percent.

Q. And then the rest of that sentence says, "Whereas approximately 80 percent of those who reported past-year heroin use had misused prescription opioids before starting heroin."

Did I read that correctly?

A. Yes, you did.

Q. And is that a fair depiction of Muhury's conclusion?

A. I think it's partially fair, but I think it's also somewhat incomplete.

Q. Okay. What would be the more complete version?

A. That 80 percent of those who used the heroin had engaged in misuse or abuse of non-medical use of prescription opioids, but that a similar number had also used illicit drugs prior to that.

Q. Right. So -- but in general, it's a true statement that four out of five heroin users began abusing prescription opioids before initiating heroin based on the current state of medical literature. Agreed?

A. That is what the Muhury, Muhury's article states, yes.

Q. Yes. I'm asking you whether you agree with that.

A. Yes, I do.

Q. And do you have any reason to -- any reasonable dispute

with the truth of that?

A. I don't have a reason to dispute it, no.

Q. Now, this McCabe article that I'm showing you got a little bit of acclaim because Dr. Compton who is at the NIH even wrote an editorial in the Journal of Addiction Medicine, a commentary. Have you had a chance to review his commentary or were you aware that Dr. Compton endorsed the McCabe article?

A. I think I'd have to look at the article in question to remember, frankly. Again, I've looked at so many articles on these topics.

Q. Does it really matter, though, if somebody -- if Dr. Compton, even if he's in NIH, does it matter if he agrees with it or not in your opinion? Does it give it weight?

A. It might.

Q. Okay.

MR. FARRELL: Judge, may I?

BY MR. FARRELL:

Q. I'll give you a chance to take a peek at it. I don't have a whole lot -- I mean, I can go through it with you, but I'll represent to you that it appears to be an acknowledgment by Dr. Compton applauding the first prospective study in your field of medicine regarding the gateway effect. Is that a fair and accurate

depiction of Dr. Compton's commentary?

A. I think I, I would, frankly, have to read through it to assess if it's a fair and accurate summary of it.

Q. Okay. Well, how about we go and look at the very first paragraph, just go down to the middle of it where it says "Key Findings."

It says, "Key findings include an overall association of both non-medical and medical use of opioid analgesics with transition to heroin use with particular concerns about early non-medical use."

This is, this is Dr. Compton's interpretation of the McCabe article. So do you have any reason to dispute the key findings of the McCabe article that I showed you?

A. I, I don't have a reason to dispute the findings, no.

Q. Okay. Well, I guess I'm just trying to fish around to see whether or not you give weight to Dr. Compton's commentary before we get into the McCabe article.

A. Yes. But, again, I'd have to read through it. It's not a very long article, but I'd have to read through it to have a full opinion on it.

Q. That's fair. Why don't we just go straight to the McCabe article.

If we can go to Page 3 of the McCabe article, under the discussion section, the very first sentence says, "This is the first national prospective study to examine the

relationships between adolescents' prescription opioid use and misuse and subsequent heroin use over a 17-year period."

So do you understand what that sentence means, that description of the study?

A. Yes, I do.

Q. And does that give you, having looked at it now, any -- I'm trying to lead you -- any recollection as to what this article is or whether or not you've read it before?

A. I believe that I have read it before. And I think it's -- what, what it describes is a prospective look at this question of prescription opioid misuse, abuse, use and individuals who initiate heroin use.

Q. Does this article have weight in your field?

A. I think it has some weight, yes.

Q. Basically, what they did was they studied -- over a period of 17 years, they studied over 11,000 high school kids and tracked them to age 35 and looked at and measured the relationship between those that have used and were prescribed prescription opioids and those that initiated heroin. Agreed?

A. Yes. Again, in an article like this, there's quite a bit of detail. So there may be many different points. But I think that's one of the things that it covers, yes.

Q. And what it found was that it wasn't four out of five. What it found was that nearly one -- it went in the other

direction with initiation. It said nearly one in three adolescents who reported non-medical prescription opioid misuse went on to report heroin use.

This article stands for the proposition that there's a greater relationship between abusing medical prescription opioids -- I'm sorry -- that there's a greater relationship between non-medical use of opioids and initiation of heroin than we ever thought. That's the conclusion of this article. Agreed?

MR. SCHMIDT: Objection, compound and characterization.

THE COURT: Well, I'll sustain the objection. You can try again, Mr. Farrell.

BY MR. FARRELL:

Q. Dr. Gilligan, did you understand my question?

A. I think so. Could you repeat the question, please?

Q. Yes. I'm going to try to repeat it in simpler terms.

This article, this, this McCabe article stands for the proposition that abusing prescription opioids has a much higher relationship to the initiation of heroin than the medical community had ever thought before. Agreed?

A. I think, again, I'd have to read through the, the article to make a real statement about what all of its conclusions are.

Q. Okay. Sir, have you read the book Dreamland?

A. Yes, I have.

Q. And in Dreamland it too talks about the sequencing of prescription opioids to heroin, does it not?

A. Among other things, yes.

Q. So I guess ultimately what I'm asking is this. If a community is overwhelmed or flooded with prescription opioids -- assume that to be a fact. I know it may be disputed. But let's just in a fictional world take 81 million pills and drop it into a community of 100,000 people. Would you expect that community to see a higher incidence of heroin initiation over time?

A. I think if there are a large number of medications prescribed in any area, there will be some of them that will be diverted, misused, abused. And, so, that there would be some incidence then where that diversion leading to misuse abuse, there would be some instances where that would lead to someone initiating heroin. I think that would be statistically likely in any area with a large number of opioid pain medications that were prescribed.

Q. And, so, when you look at it from a statistical standpoint, as the number or the volume of pills would grow higher per capita, would you also expect there to be a parallel increase in diversion and heroin initiation?

MR. SCHMIDT: Objection, foundation.

THE WITNESS: I think a process --

THE COURT: Just a minute. Overruled.

If you understand the question, you can answer it, Dr. Gilligan.

THE WITNESS: I think I understand it.

I think it could be in line with what's in that book Dreamland, but I think it would be very, very multifactorial.

BY MR. FARRELL:

Q. Sure.

A. So, I mean, that book Dreamland talked about changes and how heroin got distributed, talked about socioeconomic risk factors, also talked about volume of prescribing. So I think those sort of processes by their nature are very, very multifactorial.

Q. Is that called -- in pharmaceutical terms is that compounding? Is that -- these factors sometimes compound on top of each other?

A. No. Compounding in pharmaceutical is something very technical. It's when they essentially sort of make a custom medication for you.

Q. Now, you do recall that Dreamland is premised in the Ohio River Valley?

A. I do.

Q. And you're actually in the Ohio River Valley today.

A. Correct.

Q. And that Dreamland is the name of a pool in Portsmouth, Ohio, which if you hopped in the Kanawha River here you would float down to it?

MR. RUBY: Your Honor, I'm not sure of the relevance.

THE COURT: Where are you going with this, Mr. Farrell?

MR. FARRELL: I'm getting there soon. I'd ask for just a little bit of leeway to try to establish prescribing patterns.

THE COURT: Well, I'll sustain the objection to the last question but --

MR. FARRELL: Judge, to be --

THE COURT: You said Dreamland is the name of a pool which if you hopped into the river, bla, bla, bla. I sustain the objection to that portion.

BY MR. FARRELL:

Q. So to eliminate any debate in this courtroom, you agree and embrace the gateway effect that there does exist in scientific terms a relationship, a direct relationship between the use and abuse of prescription opioids and initiation of heroin?

A. I think there's a direct relationship that includes the misuse and abuse of prescription opioids, along with many other predisposing factors that, that then does relate to

initiation of heroin.

Q. So the gateway effect is true?

A. Again, there, there is a transition that can occur that includes many factors including misuse and abuse of prescription opioids, along with other risk factors that can lead to the initiation of heroin.

Q. Dr. Gilligan, do you recall giving a presentation in 2014, The Interventionalist's Perspective on Psychology and Outcomes?

A. Yes, I do.

Q. I have your slide deck.

MR. FARRELL: Judge, if I may, I'd like to approach.

THE WITNESS: Thank you.

BY MR. FARRELL:

Q. Dr. Gilligan, do you recognize this document?

A. Yes, I do.

Q. What is it?

A. It's a slide deck from a presentation that I gave to a group of physicians at a conference on pain medicine.

Q. And did you prepare this document?

A. Yes, I did.

Q. Did you intend this document to be educational for the purposes in which you presented it?

A. Yes, I did.

MR. FARRELL: Judge, we'd ask for P-41958 to be admitted into the record.

THE COURT: Is there any objection?

MR. SCHMIDT: Yes, there is, Your Honor. It's hearsay. I think they're trying to impeach him with it. That's just impeachment.

THE COURT: I'm not going to admit it, Mr. Farrell, but you can use it as a basis to question about what's in it.

MR. FARRELL: Judge, respectfully, if I can create a record, it's not hearsay. And if it is, it falls within the catch-all because the author of the document is sitting in the chair. And any confusion or any question about the veracity of the document can be raised with the author who's sitting in the chair.

THE COURT: What are you referring to as the catch-all, Mr. Farrell?

MR. FARRELL: 807.

THE COURT: Okay, residual exception.

MR. FARRELL: Yes, sir.

MR. SCHMIDT: Your Honor, my understanding is we've previously dealt with this issue. We dealt with this issue with Dr. O'Connell when she testified when we tried to use some of her slides. And I think Your Honor said they could be used for impeachment but not admitted into the

evidence. We think the same ruling should apply here.

MR. RUBY: And, Your Honor, if you look, Judge, at 807(b) there's a notice requirement there in that rule that I don't believe has been satisfied unless the notice was given to Mr. Schmidt.

MR. SCHMIDT: No, it wasn't.

MR. FARRELL: I'll withdraw it, Judge, and we'll just show it up on the screen.

BY MR. FARRELL:

Q. Dr. Gilligan, there's a Bates stamp that is artificially created by our numbering system. I'd like for you to go look at the bottom right-hand page which is -- it says P-41958 and then it's actually Page 29, so the underscore 00029. I have it up on the screen if you'd like to use the screen.

MR. SCHMIDT: Your Honor, if it's not being admitted, then it should be used for impeachment as opposed to showing it to him and walking through it.

THE COURT: Well, this is cross-examination. I'm going to allow it.

Go ahead, Mr. Farrell.

BY MR. FARRELL:

Q. Dr. Gilligan, did you prepare this slide? It says "Rising Sales, Abuse and Deaths."

A. Yes, I did.

Q. Okay. Would you tell the Judge what this slide means and what the purpose of this slide was?

A. So this was shown to change over time and sales of prescription opioids which, which correlates with prescriptions of opioid pain medications. That's the green line.

The purple line is deaths from drug overdoses. And the orange line is admissions for treatment of addiction.

Q. And what conclusions, if any, can you draw from these three trends?

A. So the conclusion that I can draw is that as prescriptions went up, deaths and treatment for addiction went up as well.

Q. And so what, what -- how would you describe that relationship? What's the point of putting this slide in your slide deck?

A. The point is that over-prescribing by doctors correlated with an increase in treatments for addiction and with an increase in overdoses.

Q. And to be fair, it doesn't say "over-prescribing." You used a different word, did you not?

A. I used the word that the CDC -- this is a graphic from the CDC and they use "sales." But with a prescription medication, sales is prescriptions. They're one for one.

Q. Well, that's not exactly true, is it? A prescription

is one prescription on a pad. This is tracking sales by kilogram, is it not?

A. It's number of prescriptions that -- not a kilogram or a gram of the medication leaves the pharmacy without a prescription. So prescription medication sales how to be measured correlates with prescriptions for that medication.

Q. I'm sorry. I think we're speaking past each other. The measurement on this is by kilogram of the pills, not by the number of written prescriptions?

A. Oh, correct. The unit that CDC used was, was, was sales per kilogram, yes.

Q. All right. Now, if you go to the very next page, this is Bates stamp Page 30. Will you describe what this slide is and why you included it in your slide deck?

A. Sure. So this is showing similarly where there was a lot of prescribing. This is obviously a map of the U.S. where the dark green is, dark green is where there was more prescription of pain, opioid painkillers. And the dark purple is where there were more drug overdose deaths. And it's showing geographically where there was more prescribing, there were more deaths.

Q. And, so, this is Slide Number 30. And since it's not in the record, I'm going to use some descriptive words so that we have a written record of this.

The top of this says "Deaths Track Sales." Correct?

A. Correct.

Q. And the first top half of the screen is the United States of America by, by state. And can you read aloud what the words are that you wrote on this slide for the green map?

A. Sure. Actually, I took the map from CDC. So it's words that they wrote. "Amount of prescription painkillers sold by state per 10,000 people 2010."

Q. And then on the bottom half there's the purple map with the purple United States. Will you read what the tag line is for that?

A. "Drug overdose death rates by state per 100,000 people 2008."

Q. And, so, what was the point of putting in one map tracking sales and in a second map tracking deaths?

MR. RUBY: Your Honor, I'm going to interpose an objection with regard to scope. The witness's testimony on direct examination went to the change in the standard of care that occurred in the medical field for prescription opioids and the cause of the standard of care.

Asking him to testify about, about these slides titled "Deaths Track Sales" or slides along those lines, that's beyond the scope of his direct testimony.

THE COURT: Well, what's your response to that, Mr. Farrell?

MR. FARRELL: I strongly disagree.

MR. ACKERMAN: Your Honor, I would further note that we have made numerous scope objections in our part of the case and you have said if there is a good faith basis to question the witness on cross-examination that the defendants can go ahead.

And, certainly, Mr. Farrell has a good faith basis to cross-examine a witness who is testifying about the opioid epidemic based on a slide deck that the witness put together that describes the opioid epidemic.

MR. RUBY: Your Honor, I just -- with respect to Mr. Ackerman, I don't believe that there was any ruling in the -- during the plaintiffs' case during our cross-examinations that, that the principle of scope was out the window.

THE COURT: Well, I'm going to overrule the objection. You can go ahead, Mr. Farrell.

MR. FARRELL: Thank you.

BY MR. FARRELL:

Q. So I think the last question I asked was what, what point were you trying to communicate by putting the green map in sales and comparing it to the purple map in deaths?

A. So I was trying to teach the doctors who were at the conference that where there is more opioid prescribing

geographically, where doctors prescribe more opioids, there tends to be more overdose deaths in those same areas.

Q. Now --

A. And where there's less prescribing, there are less deaths.

Q. Let me -- let's try to be accurate here on this very important point. What you were trying to demonstrate by using kilograms per capita was that the weight of prescription opioids sold in particular locations had a direct relationship to deaths. Correct?

A. No, incorrect. That's not what I was trying to teach. I was trying to teach the doctors that where you prescribe more opioids, there are more deaths, and where you prescribe less opioids, there are less deaths. It was an audience of doctors and that's what I was trying to teach them.

Q. I don't, I don't want to parse words with you. But the measuring stick in the green map is kilograms of prescription opioids, and that in states that had the more weight by kilogram per capita have a darker color. Correct?

MR. SCHMIDT: I think we've asked and answered this a few times, Your Honor.

THE COURT: I think it is. I'll sustain the objection. But I think this is relevant. I think this goes to -- it's proper cross-examination related to his testimony about the changes in the standards of care and the reasons

for it and so forth. This is consistent with his testimony concerning the reason for the change in the standard. So I think at least to that extent, it's relevant and proper cross-examination.

MR. FARRELL: But you'd like me to move on?

THE COURT: Yes. I sustain the last objection. I'm explaining my reasons for ruling in your favor the last time.

MR. FARRELL: I'm catching up.

THE COURT: Okay.

MR. FARRELL: It took nine weeks but --

BY MR. FARRELL:

Q. So if we flip to the next slide, which is Bates stamp 31, and when you look at this slide, down here at the bottom it says "Policy Impact Prescription Painkiller Overdoses," the CDC website. Do you remember where you got this picture from?

A. Yes. I got it from the CDC -- from their website or one of their documents.

Q. Okay. Is this a particular report or document? I didn't understand what the policy impact reference was.

A. Oh, I, I, I'm almost certain that that is from the CDC from their website and I think this might have been a report that they, that they had on their website as best I can recall.

Q. Okay. And would you please describe for the Judge what you were trying to communicate with this picture?
A. So what I was trying to demonstrate with that picture is that there are issues, adverse effects related to over-prescribing that went beyond just deaths; that when there's over-prescribing, deaths are a concern but there are other concerns and those are shown here.
Q. So is it fair to say that what you were trying to depict is that for every one death, you could expect to see 10 treatment admissions for abuse?
A. Correct.
Q. And for every one death, you could expect to see 32 emergency department visits for misuse or abuse?
A. Yes.
Q. And that for every one death, you would expect to see 130 people who abuse or are dependent?
A. Yes.
Q. And for every one death, you would expect to see 825 non-medical users?
A. Correct.
Q. Have you done any research to study how many deaths happened in Huntington, Cabell County, West Virginia?
A. No, I have not.
Q. The next thing we're going to go to is --
MR. FARRELL: Gina, can you bring up the Seattle

lecture?
BY MR. FARRELL:
Q. You were in Seattle recently and gave a lecture, did you not?
A. Not quite. I gave that lecture in -- at a conference in Las Vegas. But the Seattle Science Foundation is the group that chairs the lectures.
Q. I apologize. I saw Seattle down there and I just made the assumption. Is this your slide deck from your presentation?
A. I believe it is, yes.
Q. And, actually, that's not true. This isn't your slide deck. This is a screen shot of the video. It's on YouTube. Are you aware of that?
A. Yes, I am.
Q. And, so, it's got a lot of hits. The -- can you tell the Judge who you were speaking to at -- during this lecture?
A. So it was to a group of doctors and other clinicians.
Q. Was it well-attended? Was it a big event?
A. Yes, something like 200, 300, something like that.
Q. Okay. And the name of this is "Who's to Blame and Who's to Pay for the Opioid Crisis?" Did you come up with that title?
A. No. The organizers asked me -- gave me that title,

asked me to speak on that title.

Q. It happens to me all the time when they want something catchy to get people's attention. This is your, this is --

MR. SCHMIDT: I would object to that characterization.

BY MR. FARRELL:

Q. So I could play the 10 minutes because -- why did you only have 10 minutes?

A. Again, that's the organizers.

Q. Yeah. I mean, it was fantastic, but it was 10 minutes. I could play it but, instead, what I'm going to do is I'm going to try to avoid objections by taking screen shots and having you replicate it.

So if we can go to the next slide which is the first slide that you began talking about. And do you recall telling the panel or telling the group about this, this slide?

A. Yes, I do.

Q. And, so, this slide is the first slide. And will you describe what the slide is to the Court, to the Judge?

A. Sure. So it's showing over time in the U.S. the number of drug overdose deaths. And the period is 1980 to 2018. And then there are some other references -- we can all read them -- peak car crash deaths, HIV deaths, and so forth.

Q. And, so, you, you made two comments in here that I'd

like to follow up on. One of them is you said that there was a stark increase. Can you, can you talk to the judge about the nature of this increase and why, if at all, --

MR. SCHMIDT: And we're not objecting, based on Your Honor's prior rulings, to showing him the slides, but just kind of characterizing statements that wouldn't be admissible by themselves is not proper. If he wants to try to ask him a question and try to impeach, I think that's reasonable, Your Honor. But just characterizing what he said is out of context.

THE COURT: You need to ask him the questions, Mr. Farrell.

MR. FARRELL: Yes, Your Honor.

BY MR. FARRELL:

Q. Would you describe this chart as a stark increase?

A. It's definitely a very significant increase over time.

Q. Would you use the word yourself "stark," a stark increase?

A. I might, yes.

Q. Okay. And then the number of people up here, can you read that number?

A. 68,557.

Q. And you think that's enough people to fill an NFL football stadium?

A. Yes, I do.

Q. All right. Let's go to the very next slide. This is the next evolution in your presentation. And we're familiar with these in this litigation. But what are we looking at here?

A. So we're looking at the change in the incidence of drug overdose deaths. And on the left we're comparing 2003. On the right we're looking at 2017. And, again, as with some of the others, the darker color is when there's a higher, higher incidence or a higher rate.

Q. And you acquired this from the CDC website?

A. Correct.

Q. And it has not just 2003. It actually goes back further than that, doesn't it?

A. Correct.

Q. And in each year there's a picture of the, of the deaths that were reported in the United States. And when you look from 2003 to 2017, what does it look like happened in the Ohio River Valley?

A. The, the rate increased, or the incidence increased.

Q. Let's go to the next slide. Now, I think this is the same slide that we talked about before; correct?

A. Or similar there, either the same or similar.

Q. Now, let's go to the next one because it's a little bit different. Do you recall talking about this slide?

A. I do.

Q. All right. Would you please tell the Judge what this slide depicts and why you created it?

THE COURT: Just a minute.

MR. SCHMIDT: I apologize. I should have asked this before. Do you have a copy that we can have?

MR. FARRELL: Yes.

MR. SCHMIDT: I'd appreciate that.

MR. FARRELL: It has a bunch of them in there. It may not be all of them that we use.

BY MR. FARRELL:

Q. Okay. So did you describe this as three waves?

A. I think I did.

Q. Yes. And, so, would you tell the Court what the first wave was?

A. It is the prescription painkillers. It's the -- one of the light pink lines that you see there.

Q. So the top, the top one I'm pointing to, that's the first wave of prescription painkillers; correct?

A. Correct.

Q. And then what's the second wave?

A. It is the heroin.

Q. All right. And that would be this one here; correct?

A. Correct.

Q. And there is a stark increase in the heroin line starting somewhere around 2010. Agreed?

A. There's a significant increase in the heroin line starting around 2010, yes.

Q. And then you also said that there is this enormous fentanyl spike that happens toward the later part of 2010. Do you recall what you said about the origins of this and how this came about?

A. I recall some of what I said. I don't know if I have a complete recollection. It was a few years ago.

Q. Tell the Judge, if you would, how these three waves interplay together, if you recall.

A. So one can see the time lines. One can see the years at the bottom. And the overdose deaths from prescription painkillers happened earlier. And then there was a significant -- in many cases for people, there was a shift and in other cases --

COURT REPORTER: I'm sorry?

THE WITNESS: In many cases a, a shift from prescription painkiller abuse or misuse to abusing heroin and/or a shift to, to illicit fentanyl.

BY MR. FARRELL:

Q. So is it fair to say that it's your opinion that those that were suffering from opioid use disorder in the first wave began to shift to heroin? Are those your words?

A. They, they may well be.

Q. And the reason for the shift was because heroin was more accessible and less expensive. Those are your words. You've held that opinion, have you not?

A. I have held that opinion, yes.

Q. And that you again repeated on this stage that 80 percent of the people who were taking heroin had started with prescription opioids. Is that -- those are your words; correct?

A. Yes, they are.

Q. And you did not distinguish between medical and non-medical. In fact you said, quote, "Now, that's either prescription opioids that were prescribed to them or prescription opioids that were diverted and they got their hands on them."

Those were your words, were they not?

A. Yes.

Q. Now, do you recall your report in this case?

A. Yes, I do.

Q. And, so, you don't have it memorized I'm assuming. But what I'd like to do is I'd like to reference one particular provision. And that's on Page 23 where you make mention of -- and I'll just read it to you.

"According to the CDC, opioid prescriptions peaked and leveled off between 2010 and 2012 before beginning to fall thereafter."

And then you say, "A similar pattern occurred in West Virginia."

Do you recall making that statement?

A. Yes, I do.

Q. And you footnoted it. And one of the footnotes that you referenced were trends and patterns from a JAMA network article. Do you recall that?

A. More or less.

Q. I just have a couple of quick questions for you. I want -- I'm going to read this provision to you and ask whether or not you will agree with it for the Court.

MR. SCHMIDT: Your Honor, if he's going to read to him from an article, I'd ask that we get a copy of it.

THE COURT: Can you give him a copy of it?

MR. FARRELL: I could. It's not the normal course of how -- but, yes, I can.

MR. SCHMIDT: I think it's absolutely the normal course that if you're going to represent documents to a witness, the lawyer defending gets them.

BY MR. FARRELL:

Q. I'll withdraw that and just ask you a question and see whether or not you agree to it. Okay? Here's my question:

"Closing the path to opioid use disorder will require addressing over-prescription of legal opioids, reducing the

availability of illicit opioids, and getting patients with opiate use disorder into treatment."

Do you agree with that statement, sir?

A. Yes, I do.

MR. SCHMIDT: May we get a copy of the article?

MR. FARRELL: You can have mine.

MR. SCHMIDT: Thank you. I appreciate that.

BY MR. FARRELL:

Q. Let me ask you one more sentence and see whether you agree with this or not.

"The magnitude, severity, and chronic nature of the opioid epidemic in the United States is of serious concern to clinicians, the government, the general public, and others."

Do you agree with that statement, sir?

A. Yes, I do.

MR. FARRELL: Judge, if you'll give me a second here to clean up and --

THE COURT: Yes, sir.

BY MR. FARRELL:

Q. You mentioned the New England Journal of Medicine. And do you know Dan Longo, Dr. Dan Longo who's the editor by chance?

A. I don't think that I do, no.

Q. 2016. I'm going to circulate this to you. But, again,

this is a review article much like the 1982. This is, this is from Nora Volkow and Thomas McLellan, a review article reviewed by Dan Longo, the editor.

MR. FARRELL: Judge, may I approach?

THE COURT: Yes.

BY MR. FARRELL:

Q. I want to kind of go down to the, to the second full paragraph, "However." I'll give you a chance to read it for a second.

(Pause)

I'll represent for the record that this is March 31st, 2016, New England Journal of Medicine, 374 13, titled "Opioid Abuse and Chronic Pain - Misconceptions and Mitigation Strategies" written by Nora D. Volkow, M.D., for the National Institute on Drug Abuse.

My question to you is this: Sir, do you agree that opioid analgesics are widely diverted and improperly used? Do you agree with that statement, sir?

A. I think there is a significant amount of diversion and improper use of opioid analgesics, yes.

Q. And the widespread use of these drugs has resulted in a national epidemic of opioid overdose, deaths, and addictions. Do you agree with that, sir?

A. No, I think I would give a more -- I think that's one part of it, but I don't think that's a complete statement as

stated.

Q. Okay. What would you include with it?

A. So I think there was a contribution by the misuse and abuse of opioid pain medications, the non-medical use of opioid pain medications. But I think there were many other factors that also contributed that the authors are not, not including there, things like the illicit abuse of other illicit drugs and the other factors that we've talked about.

I think there were many factors and that that's one. And at least as it's written there, one could take away the impression that it was only one factor.

Q. And if you look down further, it says, "Second, the major source of diverted opioids is physician prescriptions."

Do you agree with that, sir?

A. Again, yes, but it's incomplete. The major source is that they're prescribed by physicians. And then the major source is people who receive them, then give them to friends or family.

Q. Right. So the pills -- you can attest today to the Court that the prescription pain pills being prescribed by doctors are being diverted across America?

A. I can attest today that when the -- when a pill is diverted that the most common scenario is a doctor prescribed it to somebody and then that person subsequently

gave it to a friend or family member, sold it to a friend or family member, had it stolen by a friend or family member, et cetera.

Q. My question to you is whether that is happening, not when it happens, but I'm looking to see whether you acknowledge that it is happening.

A. Yes, there are certainly instances where a doctor prescribes an opioid to one person and then that opioid subsequently from the patient, or the intended patient gets diverted to someone else after the fact.

Q. All right, Doctor, you -- last subject matter.

You talked earlier, if you remember the *voir dire* that I asked you whether or not you monitored other physicians. You've looked at the monitoring patterns of other physicians in your role, in leadership role in the medical community, have you not?

A. Yes, I've, I've participated in that monitoring. I've helped in some cases to design that monitoring, yes.

Q. All right. And, so, you're also aware that some of the medical literature that you've cited in your writings and a lot of the medical literature that you have cited in your expert witness report relies upon the IQVIA prescribing data. Are you familiar with IQVIA?

A. Yes, I am.

Q. So you're aware that you can track patterns of doctor

prescribing by looking at the IQVIA data?

A. I'm aware that that's one tool that people have used to try to track that, yes.

Q. So I'm going to represent to you that I have a good faith basis to ask you a couple questions about --

MR. SCHMIDT: We'll object to this. I don't think just showing him -- this is -- if I understand what this document is, this is a document we were given last night that an investigative firm has purportedly gathered from IQVIA regarding Dr. Gilligan's prescribing practices.

I don't think it's a proper subject for questioning him on without laying a foundation that he actually recognizes it, which I would be very surprised if he did given the source that it comes from. It's the company that Dr. Keller used to be -- used to work with apparently ran this report. And I think it should be taken down while we're arguing the objection.

THE COURT: I'll overrule the objection.

BY MR. FARRELL:

Q. So, Dr. --

MR. SCHMIDT: Your Honor, may I just note one other thing for the record?

THE COURT: Yes.

MR. SCHMIDT: Dr. Keller conceded in her testimony that IQVIA data has various limits. One of those limits is

it doesn't pick up hospital data.

Dr. Gilligan has spent his whole career working in a hospital, which is a further reason why showing him data that he can't verify is unreliable.

THE COURT: Well, that might be a matter for redirect.

Go ahead, Mr. Farrell.

BY MR. FARRELL:

Q. So, Dr. Gilligan, you are a pain medicine doctor; correct?

A. That's correct.

Q. So what I'll represent to you this is is the IQVIA data for pain medicine doctors in the nation and in West Virginia and then you.

UNIDENTIFIED SPEAKER: No.

MR. FARRELL: No?

UNIDENTIFIED SPEAKER: It's Massachusetts.

MR. FARRELL: Oh, it's Massachusetts.

BY MR. FARRELL:

Q. So when you look at the blue line of pain medicine and you see on the left-hand side dosage units, is this trend in the blue line consistent with what you've testified today about a general rise in prescribing and then more recently a tapering and a decline?

A. Yes, it is.

Q. And when you look at the base line of this from 5,000 up to 20,000, that's an increase of three-fold or so. Would you agree?

THE COURT: Is that Massachusetts data?

MR. FARRELL: The red data is Massachusetts. The blue data is the nation. And the line way down here is the doctor.

MR. SCHMIDT: And just so we're clear for the record, Your Honor, this is pain specialists according to however IQVIA, which no witness in this courtroom or probably a lawyer can testify to how they classify people as pain specialists based on the 70 percent of data they have which includes none of hospital data.

MR. FARRELL: This is --

THE COURT: Well, go ahead, Mr. Farrell. Let's get this done.

MR. FARRELL: There is Lacey Keller, the expert who testified that her methodology --

MR. SCHMIDT: It's actually not Dr. Keller. She didn't sponsor this.

BY MR. FARRELL:

Q. So would you agree with me that the rise from 5,000 up to around 20,000 and the tapering is consistent with the trend that you saw over time?

A. Yes, I would.

Q. And your prescribing patterns are somewhat below the national and the state averages. Would you agree with that?
A. Yes, but that's because I work with fellows. So when I see patients, I'm not the one who writes the prescription. I mean, they're trained so the prescriptions on my patients to measure them would show up between ten fellows every year. So they wouldn't show up under my name. They would show up under the different fellows' names.
Q. Well, the real point of this was not to show yours, but to show a couple of others.

MR. FARRELL: Can you bring up the next one, please?

BY MR. FARRELL:

Q. I think the next one is Dr. Philip Fisher. Do you know who Dr. Philip Fisher is?
A. Not that I remember.
Q. All right. Do you see here that the same baseline in blue and red but for West Virginia but the scaling is off. Do you see that?

MR. SCHMIDT: Your Honor, we're now examining based on data he can't sponsor about a doctor he said he doesn't know.

MR. FARRELL: This is directly --

MR. SCHMIDT: And I can't imagine how this is related to the scope of anything I covered, let alone the

profound foundation issues.

THE COURT: Well, I think I got the point a while ago, Mr. Farrell, and you're just beating it into the ground.

MR. FARRELL: Judge, --

THE COURT: I'll sustain the objection.

MR. FARRELL: Yes, I'm beating it into the ground. I'm trying to demonstrate overwhelmingly that this isn't a sea level change. This is a tsunami.

THE COURT: Well, I understand that's where you're going and where you've been going for half an hour and I understand that.

MR. FARRELL: So, again, you're giving me the time to move on? I'll do so.

THE COURT: Well, I'm giving you a hint that it's time to move on, Mr. Farrell.

MR. FARRELL: Yes, Your Honor.

BY MR. FARRELL:

Q. So you would agree with me that from this pictogram the data from --

MR. RUBY: Your Honor, --

THE COURT: I'll sustain the objection, Mr. Farrell.

MR. FARRELL: How about I go to the next slide? How about we put all of the slides together so that you can

see how many doctors are so far in excess of the national and state averages.

MR. SCHMIDT: Your Honor, same objection. These are doctors he hasn't reviewed with data that I don't -- tell me if I'm wrong. I don't think Dr. Keller sponsored all this data.

MR. FARRELL: The point is they just spent three hours talking about the standard of care when we have doctors that went to prison. We have doctors that exceeded the standard of care.

MR. SCHMIDT: He's -- I apologize, Mr. Farrell. I interrupted you. I didn't mean to interrupt.

Your Honor, standard of care includes wide variations, of course. And there's nothing in his testimony that denied the proposition that doctors who we have no responsibility for, who we don't regulate had the problems Mr. Farrell talked about.

We've had a witness that testified about that and you were able to cross-examine her on it. This is completely outside his scope and it's, it's completely untethered from any foundation.

THE COURT: Mr. Ruby.

MR. RUBY: Your Honor, I simply wanted to amplify, and Mr. Schmidt just said it again, that the foundation point that these are slides with data that no foundation has

been laid for. We don't know where these -- we think these came from a company that plaintiffs have paid to put slides together, but no witness has sponsored these and they're being put in front of the witness and he's being asked to testify about them as if they're evidence.

THE COURT: I'm going to sustain the objection. You've beaten the same point. If I understand your point, this was made a long time ago and I think you should move on.

MR. FARRELL: One last question.

BY MR. FARRELL:

Q. Doctor, you would agree with me that the standard of care does not immunize a doctor from blatantly breaching his obligation to do no harm?

A. I would agree with you that doctors have an obligation to do no harm. And I don't think that the standard of care would make an exception -- would justify an exception to that.

MR. FARRELL: No further questions.

THE COURT: Is there anymore?

MR. ACKERMAN: I have a couple, Your Honor.

THE COURT: Go ahead, Mr. Ackerman.

Let's take 10 minutes.

MR. ACKERMAN: Okay.

(Recess taken at 2:50 p.m.)

THE COURT: All right. Mr. Ackerman.

CROSS EXAMINATION

BY MR. ACKERMAN:

Q. Good afternoon, Dr. Gilligan. 3:00 on the Friday before July 4th weekend is not exactly prime time, so I'm going to do my best to keep this as short as possible. I want to ask you just about a couple of questions that Mr. Schmidt went through this morning.

The first one is MCWV-1522.

MR. ACKERMAN: Gina, if you can pull that up.

BY MR. ACKERMAN:

Q. And, Dr. Gilligan, I don't know if you have that in front of you. Dr. Gilligan, this is -- Document 1522 is the joint statement from 21 health organizations and the Drug Enforcement Administration, correct?

A. That is correct.

Q. And this is a -- you said it was a notice to the medical community that went out around 2001, correct.

A. That's correct.

Q. And if you would look, sir, at the second to last paragraph, the one that starts drug abuse is a serious problem. Do you see that?

A. I do.

Q. And that paragraph reads drug abuse is a serious problem. Those who legally manufacture, distribute,

prescribe and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Correct?

A. I see that, yes.

Q. And that's contained within this notice to the medical community, correct?

A. That's correct.

Q. Let's put that document aside. One more document, Dr. Gilligan, and that is the first document we went through today and I guess probably the biggest. It's MCWV-1170.

Dr. Gilligan, this is the -- this is the publication by -- I think you said it was from the Institute of Medicine; is that right?

A. That's right.

Q. And would you just remind, at least me, what is the Institute of Medicine?

A. So, it's a group of typically very well respected physicians who are tasked by the government with writing reports at different times on different health topics that are important to Americans. This report had different pain medicine specialists and then some patient representatives, et cetera.

Q. Okay. If you would turn, sir, to the page that says -- Page 163 in the little numbers in the lower left-hand corner, please, and there's a heading that says

Effectiveness of Opioids As Pain Relievers. Let me know when you're there.

A. I'm there.

Q. Okay. And do you see where it says Effectiveness of Opioids as Pain Relievers? Do you see that section?

A. I do.

Q. And there's a sentence that says the effectiveness of opioids as pain relievers, especially over the long-term, is somewhat unclear, correct?

A. I -- I see that.

Q. And then there are number of bullet points talking about different studies of the effectiveness of opioids; would you agree with that?

A. Yes, I would.

Q. And if you look at that last bullet point, it discusses a metaanalysis of studies involving back pain. Do you see that reference?

A. I do.

Q. And that sentence says a metaanalysis of studies involving back pain did not show that opioids reduced pain. Did I read that correctly?

A. Yes, you did.

Q. And then the next sentence says they also found that Substance Use Disorders are common in patients taking opioids for back pain with as many as one fourth of these

patients showing abhorrent medication taking behavior. Did I read that correctly?

A. Yes, you did.

Q. And that's one finding from the Institute of Medicine, correct?

A. That is one point that they make, yes.

Q. And do you have an understanding of what abhorrent medication taking behavior means?

A. Yes, I do.

Q. And what is that?

A. That's not taking your medications as prescribed. That's taking them -- could be more -- more frequently than prescribed, not following other instructions. For example, don't drink alcohol and take this medication and then taking them with alcohol would be an abhorrent use. So, taking them essentially and not following the instructions that were given in terms of how to take them and it would also include misusing or abusing them.

Q. Thank you. If you would then, sir, turn to the page that is number 165. Actually, I'm sorry. Further down on Page 164. Let me know when you're there. There's a heading that says Need for Education.

A. I'm there.

Q. Okay. And the last sentence of that paragraph reads, however, data from a 2009 survey conducted by SAMHSA, and

you understand what SAMHSA is, right?

A. Yes, I do.

Q. Indicate that some 5 million Americans used pain relievers non-medically in the month prior to the survey and that these medications generally were the result of a medical prescription. Do you see that sentence?

A. I do.

Q. And that's another finding of the Institute of Medicine, right?

A. That's another point that they include in their report, yes.

Q. Thank you. Now, if we go to the next page, Page 165 --

MR. ACKERMAN: And we're getting close to the end, Your Honor.

BY MR. ACKERMAN:

Q. There's a section that says Abuse of Opioids. Do you see that?

A. Yes, I do.

Q. And there's a reference here that says the diversion of opioid analgesics has become a national public health problem. Do you see that?

A. Yes, I do.

Q. And that's yet another topic that the Institute of Medicine included in this report, right?

A. Yes, it is.

Q. And if you go down to the bottom of the page, sir, there is a sentence -- there is a paragraph that reads opioid medications present some risk. Do you see that paragraph?

A. Yes, I do.

Q. And that paragraph reads opioid medications present some risk of abuse by patients, as well, and then it talks about a review of -- of studies. Do you see -- do you see where I am?

A. I think so. Structured review of 67 studies.

Q. Yes. And there's a reference at the back that says 12 percent developed abhorrent drug-related behavior. Do you see that reference?

A. I do.

Q. And that's 12 percent of chronic non-cancer pain patients regularly taking opioids; is that right?

A. That's right. The sentence has more to it. It also includes that 3 percent take a -- develop opioid abuse or addiction, as opposed to the 12 percent.

Q. Yes, yes. And you're right. The finding is that 3 percent developed opioid abuse or addiction, correct?

A. Correct.

Q. And then 12 percent developed abhorrent drug-related behavior?

A. Correct.

Q. And what -- do you have an understanding of what abhorrent drug-related behavior is?

MR. SCHMIDT: I think that was asked and answered two minutes ago, Your Honor.

MR. ACKERMAN: So, I think it's a little bit --

BY MR. ACKERMAN:

Q. Is that the same as the abhorrent medication taking behavior that we just discussed?

A. Yes. It's the same.

Q. And then the very next sentence talks about another analysis and it says a recent analysis revealed that half of patients who received a prescription for opioids in 2009 had filled another opioid prescription within the previous 30 days. Do you see that?

A. I do.

Q. And that's yet another finding that the Institute of Medicine made in this document, correct?

A. Correct.

Q. Okay. Last point, which is on the next page, Page 166, sir, there is a heading that says Opioid Use and Costs of Care. Do you see that?

A. I do.

Q. Okay. And that paragraph begins and says opioid use may increase the costs of care. Did I read that correctly?

A. Yes, you did.

Q. And that's a finding from this Institute of Medicine, right?

A. That's a point in their report, yes.

Q. Okay. And then, sir, would you read into the record the last sentence of that paragraph, which is on the next page, Page 167.

MR. RUBY: Your Honor -- Your Honor, objection. Cost of care is well beyond the scope of the direct exam.

THE COURT: Sustained.

MR. ACKERMAN: Your Honor --

THE COURT: Let's get this done, Mr. Ackerman.

MR. ACKERMAN: This is the last question, is reading this one sentence into the record, but this is a document that defendants introduced and they selectively introduced parts of it and under Rule 106 --

THE COURT: Okay. Let him read it and let's get this done.

MR. ACKERMAN: Thank you.

BY MR. ACKERMAN:

Q. Dr. Gilligan, would you please read the last sentence of this paragraph into the record?

A. A conservative estimate of the cost to society of prescription opioid abuse in the United States is $9.5 billion dollars in 2005 -- or excuse me -- $9.5 billion in 2005 dollars.

MR. ACKERMAN: Thank you.

Nothing further, Your Honor.

MR. SCHMIDT: May I proceed, Your Honor?

THE COURT: Yes.

REDIRECT EXAMINATION

BY MR. SCHMIDT:

Q. Let's pick back up with MCWV-1170 just to complete a few points regarding this Institute of Medicine study and let's start on Page 163, right where you were just asked questions about, Dr. Gilligan, under the heading Effectiveness of Opioids as Pain Relievers, and it says -- language you were just read on cross examination, the effectiveness of opioids as pain relievers, especially over the long-term, is somewhat unclear. Do you remember being asked about that language?

A. I do.

Q. Is that consistent with what you told us on direct about study data on chronic -- on the use of opioids with chronic non-cancer pain?

A. Yes. It's exactly consistent with that.

Q. Do you have an understanding as to how much of opioid use has occurred is for acute pain versus chronic non-opioid pain?

A. Excuse me. How much of opioid use is for acute pain versus chronic non-cancer pain?

Q. Yes, Doctor.

A. I'm not sure that I know an exact numerical number on that. I -- I believe that chronic non-cancer pain would be -- would be higher numbers, although I'm actually not sure numerically on that point.

Q. Okay. Fair enough. I want to just show you a couple of the findings here that we didn't get a chance to cover. The first bullet says in a metaanalysis of randomized controlled trials involving non-cancer pain, researchers concluded that the relative effectiveness and risk or benefit of opioids compared with other non-opioid treatments are still to be determined. Do you see that?

A. I do.

Q. Is that consistent with what you told us on direct?

A. Yes, that is.

Q. If you go to the next, Page 164, and let's look above that heading, Need For Education, the first paragraph above that heading. They reference those research findings above and they say the research findings noted above need to be set against the testimony of people with pain, many of whom derive substantial relief from opioid drugs. Do you see that?

A. I do.

Q. Is that consistent with what you told us on direct exam, that individual patient experiences have to be weighed

against this study data that is less conclusive?

A. Yes, it is.

Q. Let's go to Page 3. I'm sorry. Let's go to Page 165. I apologize.

You were asked about language in this section and I want to show you the second paragraph under Abuse of Opioids. And do you see there's a sentence five lines down near the end of the line that says more than half?

A. I do.

Q. More than half, 55 percent in this study of non-medical users of prescription pain relievers obtained the drugs they used most recently from a friend or relative for free; that is, they did not buy or steal them. Is that data that you've seen repeatedly throughout your work that is a concept we've heard of in court called diversion from the medicine cabinet?

A. Yes, that is.

Q. Let's go to Page 166. You were asked some questions about this section on abuse of opioids and you'll see there's language above these bullet points that say --

MR. SCHMIDT: And I'm actually going to need to capture the sentence above and then the bullet points, please.

BY MR. SCHMIDT:

Q. Current voluntary strategies to reduce opioid abuse

include, and then do you see that there is a reference to various programs?

A. I do.

Q. Do you see that the first one focuses on doctors?

A. Yes, I do.

Q. Do you see that the second one focuses on doctors?

A. I do.

Q. Do you see that the third one focuses on patients and how doctors care for patients?

A. I do.

Q. Next one talks about state Prescription Drug Monitoring Programs. Do you see that?

A. Yes, I do.

Q. Next one talks about new drug formulations by manufacturers. Do you see that?

A. Correct.

Q. And do you see the next one talks about removing unused drugs from home medicine cabinets and take-back events? Do you see that?

A. Yes, I do.

Q. Do any of those specifically speak to conduct by distributors as you understand them?

A. No, they do not.

Q. All right. And last question on this document. Do you recall being asked about the costs of opioid use?

A. Yes, I do.

Q. Let's go to Page 164, please. And right above the heading Need For Education there's some language that's italicized for emphasis. It says, regardless, the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the mis-deeds or carelessness of others. Do you have an understanding if that view of the Institute of Medicine is widely held within medicine?

A. Yes, I do.

Q. Let's go to another document, MCWV-1522. This is the 2001 joint statement from the DEA, the AMA and 20 other healthcare organizations. You were shown a sentence in the second paragraph from the bottom.

BY MR. SCHMIDT: If you can cull up that whole paragraph.

BY MR. SCHMIDT:

Q. Do you remember being asked about the second sentence to those who legally manufacture, distribute, prescribe and dispense controlled substances?

A. Yes, I do.

Q. Let's look at the very next sentence. Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated generating a sense of fear

rather than respect for their legitimate properties. Do you see that?

A. Yes, I do.

Q. And, again, did you understand that to be guidance that the medical profession and the healthcare system was receiving at this time from the DEA, from groups like the AMA?

A. Yes, I do.

Q. Let's go to your presentation, P-41958, and see if we can cull it up on the screen. And I would like to go to Page 20. Let's start on Page 30, please.

You were shown this map. And I just want to orient you to the language used where it talks about sales and kilograms. Do you see that?

A. I do.

Q. And then, if we go back to Page 29, please, again, Discussion of Sales. Do you see that?

A. I do.

Q. And there was a little colloquy between you and Mr. Farrell regarding sales for prescriptions. Why is it in these documents that you reference sales and sales per kilogram?

A. Because that's the unit that CDC uses to report it, but I used it to make a teaching point to physicians about over-prescribing.

Q. And that's what I want to see if I can understand, Dr. Gilligan. What is the relationship, if any, between sales and prescribing?

A. So, with a controlled substance that's a prescription, it's a linked relationship. There is not a sale of a gram or a kilogram without a prescription. So, sales only go up as prescriptions go up. So, sales is a surrogate for prescribing. So, that's why, since it's reported in this unit, I had to use it in this unit, but the teaching point for the doctors was entirely on over-prescribing because sales only occur when a doctor or another clinician writes a prescription.

Q. And prescriptions cause sales?

A. Yes. There is no sale without a prescription.

Q. One more question on this document. You were asked about some of the data, including the reference here to abuse. Do you see that?

A. Yes.

Q. And I want to just jump ahead to Page 32 of this document. And do you see you've provided further data on people who abuse prescription pain-killers getting their drugs from a variety of sources? Do you see that?

A. I do.

Q. And just -- if we look at three of them, obtained free from friend or relative, 55 percent, in the bottom left, and

then, upper right, the third one, took from friend or relative without asking, 4.8. And then, below that, bought from friend or relative, 11.4. Do you see that?

A. I do.

Q. And what's the data source for this data you're reporting here?

A. That's from the CDC.

Q. And so, according to this data, do we get about 70 percent of people who are abusing prescription pain-killers get them from, in one way or another, a friend or relative?

A. That's correct.

Q. Let's look at the Volkow article you were shown, P-43172, and just a couple simple questions about this article. I think you were shown language down at the bottom of the first page here in the last full paragraph where it says second. Do you see that?

A. I do.

Q. It says, second, the major source of diverted opioids is physician prescriptions. Do you see that?

A. I do.

Q. And, first of all, are you aware that this is an article from -- and we can look at the bottom, if you want. You can kind of see it down here at the bottom. 2016.

A. Yes, I'm aware.

Q. Did you understand, if we pull that down, that statement to be accurate at that time, that the major source of diverted opioids is physician prescriptions?

A. Yes, I do understand that to be accurate.

Q. They then say, for these reasons, physicians and medical associations have begun questioning prescribing practices for opioids, particularly as they relate to the management of chronic pain. Do you see that?

A. I do.

Q. How did that relate to what you told us earlier in terms of changing standards of care from the medical profession about how they prescribe or don't prescribe prescription opioids?

A. So, that's that later phase. This is from 2016, where physicians had more awareness of the potential harms, more awareness of some limitations on the data on efficacy and, therefore, started to prescribe more conservatively.

Q. Two other small points in this article. Could we go to Page 5, please? You -- when you were talking about this article, I thought I heard you give an answer about something being partly true and I thought I heard you refer to other factors being important. Am I recalling that correctly? I'm probably butchering that horribly.

A. No. I think that is a correct statement.

Q. Let me show you some specific other factors. If we

look at the left-hand column, first full paragraph in the middle, it says however. Do you see that? However, we do know that the risk of opioid addiction varies substantially among persons. Do you see that?

A. I do.

Q. Is that accurate in your view?

A. Yes, and that relates to some of the things we've talked about today.

Q. And it then says the genetic vulnerability accounts for at least 35 to 40 percent of the risk associated with addiction. Do you see that?

A. I do.

Q. And then they talk about adolescents being at an increased risk. Do you see that?

A. I do.

Q. And are these some of the factors that you were talking about that are important to consider, things like genetic vulnerability, accounting for at least 35 to 40 percent of the risk associated with addiction?

A. Yes. That's exactly an example of the sort of factors for who is going to be high risk, who's going to be medium risk, who's going to be low risk, why it's relevant to ask a patient not just do you have a history of substance abuse yourself, but do you have a family history of substance abuse. It's not a judgment on someone, but it's identifying

a risk factor in order to try to keep them safe.

Q. Let's go to Page 7, please, under Conclusions. The very bottom, it says, although there are no simple solutions, we recommend three practice and policy changes that can reduce abuse-related risks and improve the treatment of chronic pain. Do you see that?

A. I do.

Q. And then, if we go to the next page, please, we can see it hopefully culled out and it looks like the first is increased use of science supported prescribing and management practice. And then the next one is increased medical school training on pain and addiction. Do you see that?

A. I do.

Q. And the third one is increased research on pain, including potentially research on prescription opioids. Do you see that?

A. I do.

Q. Are any of those focused on distributors, as you understand them?

A. No.

Q. Let's look at the McCabe article, please, P-43594. This is the one from 2021, the longitudinal study. And let's just look at some language we didn't have a chance to see.

If we look in the bottom right corner of the first page in this article it says most adolescents who are prescribed opioids use them appropriately without an increased risk for substance misuse. Do you see that?

A. I do.

Q. Is that consistent with the broader data, as you understand it?

A. Yes. That is consistent with the broader data.

Q. And then you were asked about a commentary on this article from Compton. Do you remember that?

A. I do.

Q. Let's look at that very quickly, P-41929, and it looks like they have a summary of their commentary here. Do you see that?

A. I do.

Q. They talk about the McCabe study. Do you see that reference?

A. I do.

Q. And then they talk about the key findings. Do you see that?

A. I do.

Q. And the key findings that they reference are an overall association. Do you see that?

A. I do.

Q. And we talked about this earlier, but I just wanted to

be clear. What is the difference between association and causation?

A. So, an association is two things that have happened together that go together, but they may not be one causing the other, but there might be other causes that are just causing the two things to occur at the same time, for example.

Q. And do you remember --

MR. SCHMIDT: If we can pull that page down, but keep the document.

BY MR. SCHMIDT:

Q. Do you remember being asked about an earlier Compton article?

A. Yes, I do.

Q. Let's take a look at that earlier Compton article really quickly, DEF-WV-2646. Do you recognize this as a publication by Wilson Compton, New England Journal of Medicine?

A. Yes, I do.

Q. And the title is Relationship Between Non-Medical Prescription Opioid Use and Heroin Use. Do you see that?

A. I do.

Q. So, is this another example of analyzing people who are misusing prescription opioids and seeing if that happens before heroin use?

A. Yes, it is.

Q. Let's look at Page 7, please, of this article. Under the conclusions, let's look at the second paragraph, please.

The transition from non-medical use of prescription opioids to heroin use appears to be part of the progression of addiction in a sub-group of non-medical users of prescription opioids primarily among persons with frequent non-medical use and those with prescription opioid abuse or dependence.

Let me stop there. What do you understand that to be saying?

A. So, they're saying when people go from non-medical use of opioid pain-killers to using heroin, that that's part of a progression of an addiction among this group of non-medical users who frequently engage in the non-medical use.

Q. And when -- when you have, from your experience and your understanding of the science, when you have a progression of addiction from one substance to another, can you say that that same path wouldn't be followed by other substances if you took out one substance in the pack?

A. No, you can't.

Q. The next sentence says, although some authors suggest that there is an association between policy driven reductions in the availability --

MR. FARRELL: Judge, I'm going to object to this because I don't want to have to redirect. This is outside the scope and talks about PDMP and state laws and the impact on opioid prescribing.

THE COURT: Well, that's right, isn't it, Mr. Schmidt?

MR. SCHMIDT: I think that is true, but this is an article he was asked about, and it goes to the subject that he was asked about in terms of links between prescription opioid misuse and heroin.

THE COURT: Well, overruled. Go ahead.

BY MR. SCHMIDT:

Q. It says, although some authors suggest that there is an association between policy driven reductions and the availability of prescription opioids and increases in the rates of heroin use, the timing of these shifts, many of which began before policies were robustly implemented makes a causal link unlikely. Do you see that?

A. Yes, I do.

Q. What do you understand that to mean?

A. That what they're saying is that the shift from people who were misusing prescription opioids, abusing them, shifting to heroin was not driven by policies of decreased opioid prescribing, that the timing doesn't add up and that you can't say there was causation there.

Q. Let's look at what they say immediately below that and I'll go on to just one or two more topics.

They say, alternatively, heroin market forces, including increased accessibility, reduced price, and high purity of heroin appear to be major drivers of the recent increases in rates of heroin use. Do you see that?

A. Yes, I do.

Q. Are you familiar from the scientific literature with studies, some discussed in this article, talking about the influence of heroin market forces, including increased accessibility, reduced price in high purity, and serving as major drivers of increases in heroin use?

A. Yes, I am.

Q. I'm going to take a gamble, if I could, and see if I can go back to the white board and hope that it's there still. That didn't work. Let me try one more time.

MR. SCHMIDT: If that doesn't work, I'll move on, Your Honor.

It's not there. Okay.

BY MR. SCHMIDT:

Q. Do you remember the white board we drew with the numbers? I think it was 79.5 percent who -- of people who had used heroin who had previously used prescription opioids?

A. Yes, and it was 79.5 percent.

Q. I may get the number wrong, but I think it was 98.9 percent of the same number of people who had used heroin had used other illegal drugs?

A. Yes, and it was 98.9 percent.

Q. Okay. With that idea in mind, you talked in the context of talking about the Seattle talk given in Las Vegas that people transitioned. Do you remember being asked questions about that?

A. Yes, I do.

Q. In the same way, did people transition from using those illegal drugs to using illegal heroin and fentanyl?

Oh, and there it is. So, let me ask my question again.

You talked about the number of people who transitioned from misuse of prescription opioids to heroin. Do you remember that?

A. I do.

Q. And in the same way that a number of people transition from using these illegal drugs, cocaine, crack, marijuana, others to heroin?

A. Yes, they did.

Q. And are there other factors beyond those discussed in some of these studies, like the mental health history, the family history, discussed in the article that also contributed to this transition?

A. Yes, because those are the risk factors that predispose

to substance abuse in general, including these different types.

Q. Does the risk of someone transitioning vary by medication?

A. I think it does in the sense that there are some people who are going to be at higher risk to transition to heroin than others.

Q. And do you know how much different, if any, heroin rates would be if this type of illegal drug abuse were exactly the same and there was less misuse of prescription opioids? Can we tell that?

A. No. I don't think you can tell that.

Q. I want to just touch on two more small topics.

From your experience as a doctor, does every prescription medicine carry some form of risk?

A. Yes.

Q. And as you prescribe a medication with known risks at a higher level, as doctors do across society, do you expect to see more of the known risks of the medicine, whatever they might be?

A. Yes. If you prescribe a higher -- or doctors in general prescribe a higher volume of a given medication, you will see more of whatever the adverse effect associated with that medication is in general, yes.

Q. So, why do doctors prescribe medications?

A. Because they're -- at least with that individual patient, at that moment, they made a judgment. They might -- hopefully, it would be right, almost always, but in some cases it might even be wrong. But their judgment at that moment was that the benefits for that patient outweighed the risks and, therefore, justified prescribing that medication at that dose at that time.

Q. When you studied and looked for changes in the standard of care under which opioid prescribing went up, as I understood your testimony earlier, doctors became more aware over time of the risks of addiction and things -- and associated problems; is that fair?

A. That's correct. Over time, doctors gained an increasing awareness of the risks of opioid pain medications.

Q. Were doctors always aware, though, that there was some risk of addiction with prescription opioids throughout that time period you were looking at?

A. Yes. Throughout that time period and, actually, for many -- for decades. Prior to that, doctors have known that those medications have risks, including abuse, addiction, et cetera.

Q. Did they understand risks of death even?

A. Yes.

Q. And so, why did they prescribe more from your

understanding?

A. Again, because of this balance of risk versus benefit, that their feeling was that, in those instances, the benefits outweighed the risks.

Q. Do you know of distributors playing any role in that process?

A. Distributors played no role in that process.

Q. Last question. You were asked about a -- last set of questions. I'm sorry.

You were asked about a book called Dreamland. Do you remember being asked about that, Dreamland, that book that you said you read?

A. Yes, I do.

Q. Do you recall in that book whether there are chapters and chapters talking about the role of Purdue?

A. There were, yes.

Q. Do you recall whether there are chapters in that book talking about drug cartels and new steps they took to get heroin to people, aggressive new delivery techniques making it like pizza?

A. Yes. I remember that.

Q. We looked through that book. We couldn't find any mention of distributors. Do you recall any discussion of distributors in there?

A. I don't remember any discussion of distributors in that

book.

Q. We looked through that book. We couldn't find any mention of AmerisourceBergen, McKesson, Cardinal. Do you recall any reference to them in that book?

A. I don't recall any reference to the distributors in that book.

MR. SCHMIDT: Thank you, Dr. Gilligan.

THE COURT: Do you have anything else?

MR. FARRELL: No, Your Honor.

THE COURT: May I excuse Dr. Gilligan?

Thank you, sir, very much. You're free to go.

THE WITNESS: Thank you, Your Honor.

THE COURT: We appreciate it.

THE WITNESS: Thank you.

THE COURT: Are we done until next Wednesday? Everybody say yes.

SIMULTANEOUS SPEAKERS: Yes, Your Honor.

THE COURT: All right. I hope everybody enjoys the holiday and I'll see everybody Wednesday morning at 9:00.

(Trial recessed at 4:10 p.m.)

CERTIFICATION:

I, Ayme A. Cochran, Official Court Reporter, and I, Lisa A. Cook, Official Court Reporter, certify that the foregoing is a correct transcript from the record of proceedings in the matter of The City of Huntington, et al., Plaintiffs vs. AmerisourceBergen Drug Corporation, et al., Defendants, Civil Action No. 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as reported on July 2, 2021.

S\Ayme A. Cochran
Reporter

s\Lisa A. Cook
Reporter

July 2, 2021
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